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code of federal regulations

Public Health

42

PARTS 61 TO 399
Revised as of October 1, 1982

002-003-94850-3

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THE NATIONAL ARCHIVES OF THE UNITED STATES
1934

code of federal regulations

Public Health

42

PARTS 61 TO 399

Revised as of October 1, 1982

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Cite this Code C F R

thus: 42 CFR 61.1

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	as of January 1
Title 17 through Title 27	as of April 1
Title 28 through Title 41	as of July 1
Title 42 through Title 50	as of October 1

The appropriate revision date is printed on the cover of each volume.

LEGAL STATUS

The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to take steps to reduce the Federal paperwork burden for individuals, small businesses and State and local governments, as well as to maximize the usefulness of information collection. One specific requirement of the Act is for Federal agencies to display an OMB control number with the information collection request.

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For a summary, legal interpretation, or other explanation of any regulation in this volume, contact the issuing agency. Inquiries concerning editing procedures and reference assistance with respect to the Code of Federal Regulations may be addressed to the Director, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408 (telephone 202-523-3517). Sales are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

JOHN E. BYRNE,
Director,
Office of the Federal Register.

October 1, 1982.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of three volumes. Volume one (Parts 1-60) contains current regulations issued under Chapter I—Public Health Service (HHS). The second volume (Parts 61 to 399) contains the remaining regulations issued under Chapter I and all current regulations issued under Chapter III—St. Elizabeths Hospital (HHS). Volume three (Part 400-end) includes all regulations issued under Chapter IV—Health Care Financing Administration (HHS). These volumes represent all current regulations codified under this title of the CFR as of October 1, 1982.

Redesignation tables for Chapter I—Public Health Service, Department of Health and Human Services and Chapter IV—Health Care Financing Administration, Department of Health and Human Services appear in the Finding Aids section of these volumes.

For this volume Linda Rice-Johnston was Chief Editor. The Code of Federal Regulations publication program is under the direction of Martha B. Girard, assisted by Robert E. Jordan.

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SUBCHAPTER E—FELLOWSHIPS, INTERNSHIPS, TRAINING

PART 61—FELLOWSHIPS

Subpart A—Regular Fellowships

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Subpart A—Regular Fellowships

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, sec. 8, 77 Stat. 400; 42 U.S.C. 216, 1857g; secs. 301, 402, 58 Stat. 691, as amended, 707, secs. 412, 422, 62 Stat. 464, 598, sec. 433, 64 Stat. 444, as amended, sec. 308, 74 Stat. 364, sec. 444, 76 Stat. 1073, sec. 3, 77 Stat. 394, secs. 394, 395, 79 Stat. 1062; 42 U.S.C. 241, 282, 287a, 288a, 289c, 242f, 289g, 1857b, 280b-4, 280b-5.

SOURCE: 31 FR 12096, Sept. 16, 1966, unless otherwise noted.

§ 61.1 Definitions.

As used in this part:

(a) "Continuation award" is an award made by the Surgeon General, within the period of support recommended by a fellowship committee, without necessity for further action by the committee.

(b) "Noncitizen national" means any person who, though not a citizen of the United States, owes permanent allegiance to the United States.

(c) "Regular fellowship" means an award to support activity not requiring performance of services for the Public Health Service.

(d) "Surgeon General" means the Surgeon General of the U.S. Public Health Service or his delegate.

(e) "Continental United States" does not include Hawaii or Alaska.

§ 61.2 Applicability.

The regulations in this subpart apply to the establishment, award, and operation of all regular fellowships awarded under the Public Health Service Act and the Clean Air Act.

§ 61.3 Purpose of regular fellowships.

Regular fellowships are provided to encourage and promote:

(a) Research and training for research relating to (1) the physical and mental diseases and impairments of man, (2) the organization, provision, and financing of health services, (3) the causes, prevention, and control of air pollution, and (4) medical library and related health sciences and communication of information.

(b) Special scientific projects for the compilation of existing, or writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health.

§ 61.4 Establishment and conditions.

All regular fellowships in the Public Health Service shall be established by the Surgeon General. In establishing a fellowship or series of fellowships, the Surgeon General shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which the fellowships are to be awarded and held.

§ 61.5 Qualifications.

In order to qualify for a regular fellowship, an applicant must:

(a) Meet the Public Health Service requirements of general suitability, including professional and personal fitness.

(b) Have been accepted by a public or other nonprofit institution for the purpose of the activity for which the fellowship is sought.

(c) Be free from any disease or disability that would interfere with the accomplishment of the fellowship purpose.

(d) If a citizen or noncitizen national of the United States, sign and file with the Surgeon General the following statement:

> I do solemnly swear (or affirm) that I bear true faith and allegiance to the United States of America and will support and defend the Constitution and laws of the United States against all its enemies, foreign and domestic.

(e) Comply with such other requirements as may be prescribed by the Surgeon General.

§ 61.6 Method of application.

Application for a regular fellowship shall be made on forms prescribed by the Surgeon General. In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his qualifications and fitness.

§ 61.7 Review of applications; committees; awards.

The Surgeon General shall appoint one or more fellowship committees to examine the qualifications of applicants for fellowships and the merits of their proposals for research, training, or special scientific projects. A fellowship committee shall submit to the Surgeon General its recommendations concerning appointments. Awards of regular fellowships shall be made in writing by the Surgeon General.

§ 61.8 Benefits; stipends, dependency allowances, travel allowances; vacation.

Individuals awarded regular fellowships shall be entitled to such of the following benefits as are authorized for the particular series of fellowship:

(a) Stipend.

(b) Dependency allowances.

(c) When authorized in advance, separate allowances for travel. Such allowances may not exceed amounts prescribed by the Surgeon General for (1) travel to the place where the fellow is to be located during the fellowship term, and (2) travel to return the fellow at the end of the fellowship term to his home or other place he left to carry out the fellowship, provided that (unless otherwise prescribed by the Surgeon General) such return travel is to or from a place outside the continental United States. No allowances will be granted for shipping personal effects or household goods and no allowances will be granted for transporting dependents, except as authorized by the Surgeon General for travel undertaken by dependents (spouse and/or dependent children only) to or from a place outside the continental United States where the fellow is to be located during the fellowship term and for return from such place or except as otherwise prescribed by the Surgeon General for a particular series of fellowships.

(d) Vacation: Stipends and allowances will not be increased, or be paid beyond the term of a fellowship, on account of vacation an individual might have been entitled to but did not take.

§ 61.9 Payments—stipends, dependency allowances, travel allowances.

Payments for stipends, dependency allowances, and the travel allowances specified in § 61.8 may be made directly to the fellow or to the sponsoring institution for payment to the fellow.

§ 61.10 Benefits: Tuition and other expenses.

The Surgeon General may authorize allowances for payment of expenses, in whole or in part, of tuition, fees, equipment, supplies, attendance at meetings required to carry out the purposes of the fellowship, or other expenses of the activities of the fellow.

§ 61.11 Payments—tuition and other expenses.

(a) *Tuition and fees.* Allowances for tuition and fees may be made to the fellow or sponsoring institution.

(b) *Other expenses; standard or maximum allowances.* Any allowances for equipment, supplies, attendance at meetings, and other expenses shall, except as may otherwise be prescribed herein or by the Surgeon General, be paid to the sponsoring institution. The Surgeon General may establish a standard allowance or a maximum allowance for payment to the sponsoring institution for such expenses.

(c) *Attendance at meetings—fellows sponsored by Federal agencies.* Allowances for expenses of attendance at meetings by fellows who are sponsored by Federal agencies may be paid directly to such fellows.

(d) *Installments.* Payments to sponsoring institutions and to fellows under this section or under § 61.9 may be made in advance or by way of reimbursement and, except as may otherwise be prescribed by the Surgeon General, in monthly installments.

§ 61.12 Accountability.

Payments shall be subject to such requirements relating to accountability as may be specified by the Surgeon General.

§ 61.13 Duration and continuation.

An award period may be any period not in excess of 2 years. The Surgeon General may make one or more continuation awards for an additional period upon a finding of satisfactory progress toward accomplishment of the purposes of the initial fellowship award. Additional support may be provided on appropriate justification after expiration of the period of support involved in the previous award.

§ 61.14 Separate consideration of information concerning moral character or loyalty.

No information in the records or possession of the Public Health Service concerning the moral character or loyalty of a fellow will be made available to any fellowship committee involved in recommending appointments of fellows.

§ 61.15 Moral character or loyalty; reference to Special Review Committee; review and recommendation.

(a) *Moral character or loyalty; reference to Special Review Committee.* Whenever the Surgeon General has substantial evidence with respect to any fellow (1) that the statement filed pursuant to § 61.5(d) was not made in good faith; or (2) that a fellow has (i) been convicted of a crime involving moral turpitude or (ii) engaged in conduct involving moral turpitude (unless in the case of either paragraph (a)(2) (i) or (ii) of this section, it is established that the fellow is, nevertheless, then a person of good moral character), the Surgeon General shall refer the pertinent records to a Special Review Committee established as prescribed in paragraph (b) of this section.

(b) *Special Review Committee; composition.* The Special Review Committee shall be composed of a representative of the Office of the Surgeon General designated by the Surgeon General as chairman but nonvoting member, the appropriate Associate Director or comparable official of the bureau involved, the Chief of the Division of Research Grants, the Director of the Institute or the Chief of the Division which awarded the fellowship in question, or their delegates, and two additional members appointed by the Surgeon General.

(c) *Information; supplementation.* The Committee may supplement the information referred to it by such correspondence, personal interviews, or other informal methods as necessary in order to make its recommendation as provided in paragraph (d) of this section.

(d) *Review and recommendation.* The Committee shall review the pertinent records, determine whether there is substantial reason to believe that the award should be terminated or not continued either on grounds relating to moral character or on the ground that the statement filed pursuant to § 61.5(d) was not made in good faith, and make its recommendation to the Surgeon General in writing, with reasons therefor, accordingly.

§ 61.16 Termination of or refusal to continue award on grounds relating to moral character or loyalty; hearing.

If, after review of the recommendation of the Special Review Committee, the Surgeon General believes that the award should be terminated or should not be continued, he shall notify the fellow and sponsoring institution in writing that unless a request for a hearing is made by the fellow within 20 days after the fellow's receipt of such notice, his fellowship will be terminated or his application for continuation of the award denied. A copy of the regulations under this subpart and a copy of Part 10 of Title 45, Code of Federal Regulations, shall be enclosed with the notice. The notice shall set forth, as specifically as security permits, the grounds for the questions pertaining to moral character or loyalty. Any such request for a hearing shall be promptly submitted by the Surgeon General to the Chairman of the Departmental Fellowship Review Panel for handling in accordance with such Part 10.

§ 61.17 Termination on grounds other than those relating to moral character or loyalty.

The Surgeon General may terminate a fellowship upon receipt from the fellow of a written request for termination. The Surgeon General shall terminate any fellowship prior to the date it would otherwise expire if he determines that the fellow's performance is unsatisfactory or that the fellow or the sponsoring institution is unfit or unable to carry out the purpose of the fellowship. The fellow and the sponsoring institution shall be notified in writing of such termination.

§ 61.18 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from a fellowship awarded hereunder shall be subject to the conditions that all such materials shall bear appropriate acknowledgment of Public Health Service support, that fellows shall furnish copies of such publications or other materials as may be requested by the Surgeon General, and to such other conditions as the Surgeon General may prescribe.

§ 61.19 Copyright and reproduction.

Where the work accomplished under a fellowship award results in a book or other copyrightable material, the author is free to copyright the work, but the Public Health Service reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the fellowship award.

§ 61.20 Inventions or discoveries.

Any fellowship award made hereunder is subject to the regulations of the Department of Health and Human Services set forth in Title 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which fellowship funds are in fact used, whether within the scope of the fellowship as approved or otherwise. Appropriate measures shall be taken by the fellow, the sponsoring institution, and the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the fellowship obligation are entered into or continued and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data and information pertaining to inventions or discoveries shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those whom he may designate at such times and in such manner as he may determine necessary to comply with such Department regulations.

§ 61.21 Interest.

Any interest earned through deposit or investment by the sponsoring institution of funds paid pursuant to the provisions of this subpart shall be paid to the United States as such interest is received by the sponsoring institution.

§ 61.22 Nondiscrimination.

Attention is called to the fact that funds paid to a sponsoring institution pursuant to § 61.11 in order to meet the expenses of the activities of a fellow are considered Federal financial assistance to such institution. The institution is thus subject in this respect to the prohibition against discrimination on the basis of race, color, or national origin imposed by Title VI, Civil Rights Act of 1964, and the implementing Regulation of the Department of Health and Human Services (45 CFR Part 80).

Subpart B—Service Fellowships

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; secs. 207 and 208, 58 Stat. 685, as amended; 58 Stat. 686, as amended; 42 U.S.C. 209 and 210.

SOURCE: 31 FR 12098, Sept. 16, 1966, unless otherwise noted.

§ 61.30 Definitions.

As used in this part:

(a) "Service fellowship" is one which requires the performance of services, either full or part time, for the Public Health Service. A service fellow is an employee of the Public Health Service.

(b) "Surgeon General" means the Surgeon General of the U.S. Public Health Service or his delegate.

(c) "Continental United States" does not include Hawaii or Alaska.

§ 61.31 Applicability.

The regulations in this part apply to the establishment of service fellowships in the Public Health Service, the designation of persons to receive such fellowships, and the appointment of service fellows under authority of section 207(g) of the Public Health Service Act.

§ 61.32 Purpose of service fellowships.

Service fellowships in the Public Health Service are for the purpose of encouraging and promoting research, studies, and investigations related to health. Such fellowships may be provided to secure the services of talented scientists for a period of limited duration for health-related research, studies, and investigations where the nature of the work or the character of the individual's services render customary employing methods impracticable or less effective.

§ 61.33 Establishment of service fellowships.

All service fellowships shall be established by the Surgeon General. In establishing a service fellowship, or a series of service fellowships, the Surgeon General shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which service fellows will be appointed and will hold their fellowships.

§ 61.34 Qualifications.

Scholastic and other qualifications shall be prescribed by the Surgeon General for each service fellowship, or series of service fellowships. Each individual appointed to a service fellowship shall (a) have presented satisfactory evidence of general suitability, including professional and personal fitness; (b) be free from any disease or disability that would interfere with his carrying out the purpose of the fellowship; and (c) possess any other qualifications as reasonably may be prescribed.

§ 61.35 Method of application.

Application for a service fellowship shall be made in accordance with procedures established by the Surgeon General.

§ 61.36 Selection and appointment of service fellows.

The Surgeon General shall (a) prescribe a suitable professional and personal fitness review and an examination of the applicant's qualifications; (b) designate in writing persons to receive service fellowships; and (c) establish procedures for the appointment of service fellows.

§ 61.37 Stipends, allowances, and benefits.

(a) *Stipends.* Service fellows shall be entitled to such stipend as is authorized by the Surgeon General for each service fellowship or series of service fellowships.

(b) *Travel and transportation allowances.* Under conditions prescribed by the Surgeon General, an individual appointed as a service fellow may be authorized travel allowances or transportation and per diem for himself, travel allowances or transportation for his immediate family, and transportation of household goods and personal effects, in conjunction with travel authorized by the Service (1) from place of residence, within or outside the continental United States, to first duty station, (2) for any change of duty station ordered by the Service during the term of the fellowship, and (3) from last duty station to the place of residence which he left to accept the fellowship, or to some other place at no greater cost to the Government. A service fellow shall be entitled to travel allowances or transportation and per diem while traveling on official business away from his permanent duty station during the term of the fellowship. Except as otherwise provided herein, a service fellow shall be entitled to travel and transportation allowances authorized in this part at the same rates as may be authorized by law and regulations for other civilian employees of the Public Health Service. If a service fellow dies during the term of a fellowship, and his place of residence which he left to accept the fellowship was outside the continental United States, the payment of expenses of preparing the remains for burial and transporting them to the place of residence for interment may be authorized. In the case of deceased service fellows whose place of resident was within the continental United States, payment of the expenses of preparing the remains and transporting them to the place of residence for interment may be authorized as provided for other civilian employees of the Public Health Service.

(c) *Benefits.* In addition to other benefits provided herein, service fellows shall be entitled to benefits as provided by law or regulation for other civilian employees of the Public Health Service.

(d) *Training.* Service fellows are eligible for training at Government expense on the same basis as other civilian employees.

§ 61.38 Duration of service fellowships.

Initial appointments to service fellowships may be made for varying periods not in excess of 2 years. Such appointments may be extended on a year-to-year basis in accordance with procedures and requirements established by the Surgeon General.

PART 62—NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM

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Sec.
62.14 What are the special provisions relating to recipients of awards under the PH/NHSC scholarship training program who will also receive awards under the scholarship program?

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 751 of the Public Health Service Act, 90 Stat. 2281 (42 U.S.C. 294t).

SOURCE: 45 FR 55429, Aug. 20, 1980, unless otherwise noted.

§ 62.1 What is the scope and purpose of the National Health Service Corps scholarship program?

These regulations apply to the award of scholarships under the National Health Service Corps Scholarship Program authorized by section 751 of the Public Health Service Act (42 U.S.C. 294t) to students receiving academic training in medicine, osteopathy, dentistry, and other health professions. The purpose of this program is to assure an adequate supply of trained health professionals for the National Health Service Corps which is used by the Secretary to improve the delivery of health services in health manpower shortage areas.

§ 62.2 Definitions.

As used in this part:

"Acceptable level of academic standing" means the level at which a full-time student retains eligibility to continue in attendance in school under the school's standards and practices.

"Act" means the Public Health Service Act, as amended.

"Approved graduate training" means those programs of graduate training in medicine, osteopathy, dentistry or other health professions which (a) lead to eligibility for board certification or which provide other evidence of completion, and (b) have been approved by the appropriate health professions body as determined by the Secretary.

"Full-time student" means an individual pursuing a course of study leading to a degree in medicine, osteopathy, dentistry or an equivalent credential for a particular health profession who is enrolled for a sufficient number of credit hours in any academic term to complete the course of study within not more than the number of academic terms normally required at the school. If an individual is enrolled in a school and is pursuing a course of study which is designed to be completed in more than 4 years, the individual will be considered a full-time student for only the last 4 years of the course of study.

"Health manpower shortage area" means the geographic area, the population group, the public or nonprofit private medical facility, or other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulations (42 CFR Part 5).

"National of the United States" means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"Public Health and National Health Service Corps Scholarship Training Program", or "PH/NHSC Scholarship Training Program", means the program authorized by section 225 of the Act as in effect on September 30, 1977, and repealed on October 1, 1977.

"Scholarship Program" means the National Health Service Corps Scholarship Program authorized by section 751 of the Act (42 U.S.C. 294t).

"Scholarship Program participant" or "participant" means an individual whose application to the Scholarship Program has been approved and whose contract has been accepted and signed by the Secretary.

"School" means a school of medicine, osteopathy, dentistry, or other health profession which (a) provides training leading to a degree of doctor of medicine, doctor of osteopathy, doctor of dentistry, or an equivalent credential for a particular health profession, and (b) which is accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

"School year" means all or part of the 12-month period from July 1 through June 30 during which an applicant is enrolled in a school as a full-time student.

"Service" means the United States Public Health Service.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 62.3 Who is eligible to apply for a scholarship program award?

(a) To be eligible for a scholarship under this part an applicant must:

(1) Be accepted for enrollment, or be enrolled, as a full-time student in a school located in a State;

(2) Be pursuing a course of study or program offered by the school leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession;

(3) Be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the National Health Service Corps;

(4) Be a National of the United States; and

(5) Submit an application to participate in the Scholarship Program together with a signed contract as described in section 751(f) of the Act.

(b) Any applicant who owes an obligation for professional practice to a State or other entity under an agreement entered into before filing an application under this part is ineligible for an award unless a written statement satisfactory to the Secretary is submitted from the State or entity that (1) there is no potential conflict in fulfilling the service obligation to the State or entity and the Scholarship Program, and that (2) the Scholarship Program service obligation will be served before the service obligation for professional practice owed to the State or entity.

(c) Any individual who receives a scholarship under the Indian Health Service Scholarship Program (section 757 of the Act) or the Scholarship Program for First-Year Students of Exceptional Financial Need (section 758 of the Act) is ineligible to participate in the Scholarship Program during the School year(s) for which the scholarships under sections 757 or 758 of the Act were awarded.

§ 62.4 To whom will scholarship program awards be available in addition to those individuals pursuing courses of study leading to degrees in medicine, osteopathy, or dentistry?

The Secretary will, from time-to-time, publish in the FEDERAL REGISTER a list of those health professions in addition to medicine, osteopathy, and dentistry for which the National Health Service Corps has need and for which support is available. The Secretary will also publish any other eligibility criteria, in addition to those in § 62.3, that may be required to assure that participants can be utilized during their periods of obligated service in a manner that will best meet the needs of the National Health Service Corps.

§ 62.5 How is application made for a scholarship program award?

Each individual desiring a scholarship under this part must submit an application (including a signed contract as required under section 751(f) of the Act) in the form and at the time prescribed by the Secretary.

62.6 How will individuals be selected to participate in the scholarship program?

(a) *General.* In deciding which applications for participation in the Scholarship Program will be approved, the Secretary will place the applications into categories based upon the selection priorities described in paragraph (b) of this section. Except for continuation awards (see paragraph (e) of this section) the Secretary will then evaluate each applicant under paragraph (c) of this section.

(b) *Priorities.* (1) First priority will be given to individuals who have previously received a scholarship under the PH/NHSC Scholarship Training Program, a scholarship under this Scholarship Program, or a scholarship under section 758 of the Act, authorizing scholarships for first-year students of exceptional financial need. (2) Second priority will be given to applicants who are entering their first year of study.

(c) *Selection.* (1) In selecting participants, the Secretary will take into consideration those factors which he or she determines necessary to assure effective participation in the Scholarship Program. These factors may include, but not be limited to (i) work experience, (ii) community background, (iii) career goals, (iv) faculty recommendation, and (v) academic performance.

(2) Special consideration will be given to (i) medical and osteopathic students who indicate their intention to enter family practice, internal medicine, pediatrics, or osteopathic general practice residencies, (ii) dental students who indicate their intention to undertake general practice training following graduation or who plan no postgraduate training, and (iii) those individuals who indicate an intent to pursue other types of clinical practice or specialized training for which the National Health Service Corps has a particular need.

(d) *Duration of Scholarship award.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a participant a scholarship under this part for a period of 1 school year.

(e) *Continuation awards.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a continuation scholarship if (1) the participant requests a continuation, (2) the award will not extend the total period of Scholarship Program support beyond 4 years, and (3) the participant is eligible for continued participation in the Scholarship Program.

§ 62.7 What will an individual be awarded for participating in the scholarship program?

(a) *Amount of scholarship.* (1) A scholarship award for each school year will consist of (i) tuition, (ii) reasonable educational expenses, including required fees, books, supplies, and required educational equipment, and (iii) a monthly stipend for the 12-month period beginning with the first month of each school year in which the individual is a participant. For purposes of this section "required fees" means those fees which are charged by the school to all students pursuing a similar curriculum and "required educational equipment" means educational equipment which must be rented or purchased by all students pursuing a similar curriculum at that school.

(2) The Secretary may enter into a contract with the school in which the participant is enrolled for the direct payment of tuition and reasonable educational expenses in the participant's behalf.

(b) *Payment of scholarship: leave-of-absence; repeated course work.* The Secretary will suspend scholarship payments to or on behalf of a participant if the school (1) approves a leave-of-absence for the participant for health, personal, or other reasons, or (2) requires the participant to repeat course work for which the Secretary has previously made scholarship payments under § 62.7. However, if the repeated course work does not delay the participant's graduation date, scholarship payments will continue except for any additional costs relating to the repeated course work. Any scholarship payments suspended under this paragraph will be resumed by the Secretary upon notification by the school that the participant has returned from the leave-of-absence or has completed the repeated course work and is pursuing as a full-time student the course of study for which the scholarship was awarded.

§ 62.8 What does an individual have to do in return for the scholarship program award?

(a) *General.* Except as provided in paragraphs (d), (f), and (g) of this section, each participant is obligated to (1) become a member of the National Health Service Corps employed as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a Federal civilian in the full-time clinical practice of the participant's profession and (2) serve in the health manpower shortage area to which the participant is assigned by the National Health Service Corps.

(b) *Beginning of service.* (1) The period of obligated service will begin when the Scholarship Program participant begins to provide services in the health manpower shortage area to which he or she is assigned by the Secretary. Except for those participants who receive a deferral under § 62.9 (a) or (b), this assignment will be made by the Secretary as soon as possible following: (i) the completion of the participant's course of study leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession, and (ii) appointment of the participant as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

(2) For purposes of this paragraph, "appointment" means only those appointments as Commissioned Officers in the Regular or Reserve Corps of the Service or as civilian members of the National Health Service Corps made specifically for the purpose of serving a participant's period of obligated service.

(c) *Duration of service.* Except as provided in § 62.14(b)(1), the period for which the Scholarship Program participant is obligated to serve is equal to 1 year for each school year for which the participant receives a scholarship award under this part, or 2 years, whichever is greater.

(d) *Service by detail.* If the Secretary determines that there is no need in a health manpower shortage area for a member of the profession in which the Scholarship Program participant is obligated to provide service, the Scholarship Program participant may be detailed to serve the period of obligated service as a full-time member of the profession for which the participant has been trained, in any unit of the Department of Health and Human Services as the Secretary may determine.

(e) *Creditability of approved graduate training.* Except as provided in § 62.14(b)(2), no period of approved graduate training will be credited toward satisfying the period of obligated service incurred under the Scholarship Program.

(f) *Service under the National Research Service Award Program.* (1) A Scholarship Program participant who demonstrates exceptional promise for medical research may perform the period of obligated service owed under this section by participating in the National Research Service Award Program for individual postdoctoral fellows authorized under section 472 of the Act.

(2) Exceptional promise for medical research will be demonstrated if the participant applies for a National Research Service Award for individual postdoctoral fellows, is selected to participate in this research program, and accepts the offer of participation. A Scholarship Program participant in the National Research Service Award Program will receive credit toward satisfying the period of obligated service incurred under this section for any period of time he or she is engaged in activities which meet the service requirements of the National Research Service Award Program.

(3) If the time served under the National Research Service Award Program is less than the total period of obligated service owed under the Scholarship Program, the participant will serve the remainder of the Scholarship Program service obligation (i) in activities which meet the criteria for service under the National Research Service Award Program, as approved by the Secretary or (ii) as a member of the National Health Service Corps providing health services in the full-time clinical practice of his or her health profession. A participant who fails to begin or complete the service requirements under the National Research Service Award Program may be subject to the default penalty under § 62.10(c) of this part and the default penalties under the National Research Service Award Program.

(g) *Release from service obligation to engage in private practice.* The Secretary will release a participant from all or part of the service obligation if the participant applies for a release under section 753 of the Act and agrees in writing to engage for a period equal to the remaining period of the participant's service obligation in the full-time private clinical practice of the participant's health profession, under the requirements of section 753 of the Act.

§ 62.9 Under what circumstances can the period of obligated service be deferred to complete approved graduate training?

(a) *Requested deferment.* Upon the request of any participant receiving a degree from a school of medicine, osteopathy, or dentistry, veterinary medicine, optometry, podiatry or pharmacy, the Secretary will defer the beginning date of the obligated service to allow the participant to complete an approved graduate training program. The period of this deferment may not exceed (1) three years for any participant receiving a degree from a school of medicine, osteopathy or dentistry, or (2) one year for any participant recieving a degree from a school of veterinary medicine, optometry, podiatry or pharmacy. The Secretary may, however, extend this period of deferment if the Secretary determines that the extension is consistent with the needs of the National Health Service Corps.

(b) *Required deferment.* Each participant receiving a degree in medicine or osteopathy who does not intend to enter training which can be completed within the deferment period granted under paragraph (a) of this section must complete at least one year of approved graduate training before beginning the period of obligated service. This one year of training must be in (1) an allopathic flexible first-year program whose sponsorship includes approved residencies in family practice, internal medicine, pediatrics, or a categorical first-year program in family practice, internal medicine, or pediatrics; (2) a rotating internship in osteopathic medicine; or (3) such other programs as the Secretary determines provides comparable experience. Any participant receiving a degree in medicine or osteopathy who fails to complete the one year of required training or an approved graduate training program for which a deferment was granted under paragraph (a) of this section will be subject to the default penalties of § 62.10(c).

(c) *Altering deferment.* Before altering the length or type of approved graduate training for which the period of obligated service was deferred under paragraphs (a) or (b) of this section, the participant must request and obtain the Secretary's approval of the alteration.

(d) *Additional terms of deferment.* The Secretary may prescribe additional terms and conditions for deferment under paragraphs (a), (b), and (c) of this section as necessary to carry out the purposes of the Scholarship Program.

(e) *Beginning of service after deferment.* Any participant whose period of obligated service has been deferred under paragraphs (a) or (b) of this section must begin the obligated service when the participant begins to provide health services in the health manpower shortage area to which he or she is assigned by the Secretary. This assignment will be made by the Secretary as soon as possible following (1) the completion of the requested or required graduate training for which the deferment was granted, and (2) appointment as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

§ 62.10 What will happen if an individual does not comply with the terms and conditions of participating in the scholarship program?

(a) If a participant, other than one described in paragraph (b) of this section, fails to accept payment or instructs the school not to accept payment of the scholarship provided by the Secretary, the participant must, in addition to any service or other obligation incurred under the contract, pay to the United States the amount of $1,500 liquidated damages. Payment of this amount must be made within 30 days of the date on which the participant fails to accept payment of the scholarship award or instructs the school not to accept payment.

(b) When a participant fails to maintain an acceptable level of academic standing, is dismissed from the school for disciplinary reasons, or voluntarily terminates the course of study or program for which the scholarship was awarded before completing the course of study or program, the participant must, instead of performing any service obligation, pay to the United States an amount equal to all scholarship funds awarded under § 62.7. Payment of this amount must be made within 3 years of the date the participant becomes liable to make payment under this paragraph.

(c) If a participant fails to begin or complete the period of obligated service incurred under § 62.8, including failing to comply with the applicable terms and conditions of a deferment granted by the Secretary, the participant must pay to the United States an amount determined by the formula set forth in section 754(c) of the Act. Payment of this amount shall be made within 1 year of the date that the participant failed to begin or complete the period of obligated service, as determined by the Secretary.

§ 62.11 When can a scholarship program payment obligation be discharged in bankruptcy?

In accordance with section 754(d)(3) of the Act, any payment obligation incurred under § 62.10 may not be discharged in bankruptcy under Title XI of the United States Code until 5 years after the date on which the payment obligation is due.

§ 62.12 Under what circumstances can the service or payment obligation be canceled, waived or suspended?

(a) Any obligation of a participant for service or payment will be canceled upon the death of the participant.

(b)(1) A participation may seek a waiver or suspension of the service or payment obligations incurred under this part by written request to the Secretary setting forth the bases, circumstances, and causes which support the requested action. The Secretary may approve a request for a suspension for a period of 1 year. A renewal of this suspension may also be granted.

(2) The Secretary may waive or suspend any service or payment obligation incurred by a participant whenever compliance by the participant (i) is impossible, or (ii) would involve extreme hardship to the participant and if enforcement of the service or payment obligation would be against equity and good conscience.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as physical or mental disability, terminal illness in the immediate family which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 62.13 What are the limitations on the receipt of concurrent benefits?

Under section 741(f) or 836(h) of the Act, the Secretary may agree to repay a portion of an individual's educational loans in return for the individual's agreement to practice his or her profession in an area in need of health manpower. However, a Scholarship Program participant may not enter into an agreement with the Secretary under section 741(f) or 836(h) of the Act, until either: (a) The participant has completed the service obligation under the Scholarship Program, (b) the Secretary has recovered from the participant an amount determined under § 62.10, or (c) any service or payment obligation has been waived under § 62.12. In no case shall a scholarship received under these regulations be considered an educational loan for the purposes of section 741(f) or 836(h) of the Act.

§ 62.14 What are the special provisions relating to recipients of awards under the PH/NHSC scholarship training program who will also receive awards under the scholarship program?

(a) Except as provided in paragraph (b) of this section, if a participant has previously received an award under the PH/NHSC Scholarship Training Program and also receives an award under the Scholarship Program, the terms and conditions of these regulations will apply to the participant's entire obligation incurred under both the PH/NHSC Scholarship Training Program and the Scholarship Program.

(b) If a participant has received an award under the PH/NHSC Scholarship Training Program and also receives an award under the Scholarship Program, the following conditions apply:

(1) *Period of obligated service—carry over.* The period of obligated service owed by the participant is equal to the total number of school years for which scholarship support was awarded under both the PH/NHSC Scholarship Training Program and the Scholarship Program without regard to either Program's minimum support requirement under 42 CFR 62.7(a) (1976) as adopted on May 22, 1974 (see 39 FR 17962), and under § 62.8(c) of this part.

(2) *Credit for internship and residency training.* (i) If a participant received a scholarship under the PH/NHSC Scholarship Training Program for any school year beginning before October 12, 1976, the participant will receive credit toward satisfying the periods of obligated service incurred under the PH/NHSC Scholarship Training Program and under § 62.8 of this part for any periods of internship or residency training served in a Service or National Health Service Corps facility.

(ii) If a participant received a scholarship for the first time during the 1977-78 school year under the PH/NHSC Scholarship Training Program, the participant will only receive 1 year of credit toward satisfying the period of obligated service incurred under the PH/NHSC Scholarship Training Program for internship or residency training served in a Service or National Health Service Corps facility.

(3) *Default penalties.* The PH/NHSC Scholarship Training Program default penalty will apply to a participant who fails to begin or complete the active duty service obligation incurred under that Program, and the § 62.10 default penalties will apply to a participant who fails to begin or complete the service obligation incurred under § 62.8 of these regulations. In determining which default penalty to apply when an individual who has received a Scholarship award under both the PH/NHSC Scholarship Training Program and the Scholarship Program fails to begin or complete his service obligation, the service obligations will be considered to have been served in the order in which they were incurred.

PART 63—NATIONAL INSTITUTES OF HEALTH AND NATIONAL LIBRARY OF MEDICINE TRAINEESHIPS

Sec.

63.1 Nature and purpose of traineeships.
63.2 Minimum qualifications.
63.3 Award of traineeships.
63.4 Benefits.
63.5 Terms and conditions of award.
63.6 Termination of traineeships.
63.7 Appropriate Institute.

AUTHORITY: Sec. 215, 58 Stat. 690, secs. 301, 402, 403, 58 Stat. 691, 707, sec. 303, 60 Stat. 423, secs. 412, 422, 62 Stat. 464, 598, sec. 433, 64 Stat. 444; 42 U.S.C. 216, 241, 282, 283, 242a, 287a, 288a, 289c.

SOURCE: 21 FR 9868, Dec. 12, 1956, unless otherwise noted.

§ 63.1 Nature and purpose of traineeships.

(a) A National Institutes of Health traineeship is an award of funds to an individual for his subsistence during a period in which he is acquiring advanced training in the diagnosis, prevention or treatment of diseases of public health significance. The purpose of such traineeships is to make available in the United States for the community effort against such diseases an increased number of persons having special competence in such diagnosis, prevention or treatment.

(b) A National Library of Medicine Traineeship is an award of funds to an individual for his subsistence and other expenses during a period in which he is acquiring advanced training in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of communication of health sciences information.

[21 FR 9868, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

§ 63.2 Minimum qualifications.

Minimum qualifications for any traineeship shall be established by the Director of the appropriate Institute with the approval of the Surgeon General, and shall be uniformly applicable to all applicants in each traineeship program of such Institute. Such minimum qualifications may include requirements as to age, physical or mental condition, academic degrees, professional or other training or experience and such other factors as may be necessary to the fulfillment of the purpose of the traineeship. To the extent the Surgeon General finds it not inconsistent with such fulfillment, however, he may in individual cases waive compliance with any minimum qualification so established if he determines that the applicant has substantially equivalent qualifications or has such special training, experience or opportunity for service as make an award particularly appropriate.

§ 63.3 Award of traineeships.

Subject to the regulations of this part, the Surgeon General or his delegate may award traineeships to those qualified applicants who are best able in his judgment to carry out the purpose of the traineeships. Such awards may be made in the name of the appropriate Institute.

§ 63.4 Benefits.

Each individual awarded a traineeship shall be entitled to the following benefits:

(a) A stipend fixed in amount by the Surgeon General and payable with respect to a period of one year or such other period, including extensions or renewals, as may be specified by the Surgeon General or his delegate in making awards.

(b) An additional allowance, if requested by the trainee and approved in advance by the Surgeon General or his delegate, for travel, per diem and transportation not exceeding such amounts as may be prescribed by the Surgeon General.

§ 63.5 Terms and conditions of award.

All traineeship awards shall be subject to the following terms and conditions:

(a) Training must be carried out at an institution found by the Director of the appropriate Institute to provide a well-rounded course of instruction in the particular field in which the traineeship is awarded. A change in the training institution may be made only with the approval of such Director.

(b) No traineeship may be utilized to compensate, nor awarded as consideration, for personal services or employment of the trainee for the United States or for any other person.

(c) No payment shall be made to any citizen or noncitizen national of the United States receiving an award under the regulations in this part unless such citizen or noncitizen national has taken, subscribed to, and filed with the Public Health Service a written oath or affirmation in the following terms: "I do solemnly swear (or affirm) that I bear true faith and allegiance to the United States of America and will support and defend the Constitution and laws of the United States against all its enemies, foreign and domestic."

(d) Additional conditions consistent with the regulations in this part may be established by the Surgeon General or his delegate to the extent he finds them necessary to fulfill the purpose of the traineeship.

(e) A noncitizen national of the United States is a person, who, though not a citizen of the United States, owes permanent allegiance to the United States.

(f) Payments made under awards pursuant to § 63.1(b) may be made to the trainee or the sponsoring institution. Except as may be otherwise prescribed by the Surgeon General, payments shall be made in advance or by way of reimbursement and in monthly installments.

[21 FR 9868, Dec. 12, 1956, as amended at 30 FR 6072, Apr. 29, 1965; 31 FR 9505, July 13, 1966]

§ 63.6 Termination of traineeships.

The Surgeon General or his delegate may terminate a traineeship at any time upon request of the trainee, and shall terminate any traineeship prior to the date it would otherwise expire upon a determination, made or approved by the Surgeon General, either that the trainee's performance is unsatisfactory or that he is unfit or unable to carry out the purpose of the traineeship.

§ 63.7 Appropriate Institute.

As used in this part "appropriate Institute" shall mean the National Cancer Institute for traineeships in the field of cancer, the National Institute of Mental Health for traineeships in the field of mental disorders, the National Heart Institute for traineeships in the field of cardiovascular diseases, the National Institute of Dental Research for traineeships in the field of dental diseases and conditions, the National Institute for Allergy and Infectious Diseases for traineeships in the field of allergy and infectious diseases, the National Institute of Arthritis and Metabolic Diseases for traineeship in the field of arthritis, rheumatism and metabolic disease, the National Institute of Neurological Diseases and Blindness for traineeships in the field of epilepsy, cerebral palsy, multiple sclerosis, other neurological and sensory disorders, and any other institute hereafter established by the Surgeon General under section 431 of the Public Health Service Act, as amended, for traineeships in the field of those diseases constituting the responsibility of such institute. "Appropriate Institute" shall also mean, with respect to awards pursuant to § 63.1(b), the National Library of Medicine.

[21 FR 9868, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

PART 64—NATIONAL INSTITUTES OF HEALTH AND NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

Sec.

64.1 Nature and purpose of training grants.
64.2 Application requirements.
64.3 Award of training grants.
64.4 Conditions to awards; general.
64.5 Additional conditions; institutional expenses.
64.6 Additional conditions; stipends.
64.7 Payments; repayment of unexpended balances; unauthorized expenditures.
64.8 Appropriate Institute.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; sec. 433, 64 Stat. 444; 42 U.S.C. 289c.

SOURCE: 21 FR 9869, Dec. 12, 1956, unless otherwise noted.

§ 64.1 Nature and purpose of training grants.

(a) A National Institutes of Health training grant is an award of funds to a qualified educational or training institution, the objective of such grants being to make available for the community effort against diseases of public health significance an increased number of facilities providing adequate training and instruction, and an increased number of persons having special competence, in matters relating to the diagnosis, prevention and treatment of such diseases. Such a grant may have one or both of the following purposes:

(1) To defray the expenses of the institution in providing training and instruction in matters relating to the diagnosis, prevention or treatment of diseases within the responsibility of the appropriate Institute.

(2) To enable the institution to pay stipends and allowances to individuals with respect to a period in which they receive under the direction of such institution training and instruction in matters relating to such diagnosis, prevention or treatment.

(b) A National Library of Medicine training grant is an award of funds to a qualified educational or training institution, the objective of such a grant being to make available an increased number of facilities providing adequate training and instruction, and an increased number of persons having special competence in medical library service and science and in the field of communication of information pertaining to sciences relating to health. Such a grant may have one or both of the following purposes:

(1) To defray the expenses of the institution in providing training and instruction in medical library service and science and in communication of health sciences.

(2) To enable the institution to pay stipends and allowances to individuals during the periods in which they receive, under the direction of such institution, training and instruction in such science and communication.

[21 FR 9869, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

§ 64.2 Application requirements.

Training grants shall be awarded only to those public or other nonprofit institutions which file applications in such form and manner as may be prescribed by the Surgeon General. Such applications shall set forth, in addition to any other pertinent information that may be required, the name and qualifications of the program director who will be responsible for the training and instruction and the following information depending upon the purposes for which the grant is requested:

(a) *Institutional expenses.* Applications which include a request for funds to meet institutional expenses shall set forth the nature and duration of the training and instruction program with respect to which the application is filed, the total amount requested and the purposes for which the funds will be used, stating separately the amounts requested for personal services and the amounts requested for equipment, supplies or other non-personal expenses.

(b) *Stipends.* Applications which include a request for funds to enable the institution to make payments to individuals receiving training shall state the nature and duration of the training and instruction to be provided, and the applicant shall also furnish information concerning the minimum qualifications required of the individuals to be trained or instructed, the rate of stipend and allowances to be paid, and the total amount requested for these purposes.

§ 64.3 Award of training grants.

Subject to the regulations in this part, the Surgeon General may award training grants to such eligible public or other nonprofit institutions as are best able in his judgment to carry out the purpose of such grants. Such grants may be made in the name of the appropriate Institute, but no such grant may be made unless it has been recommended by the national advisory council for such Institute.

§ 64.4 Conditions to awards; general.

All training grants awarded under the authority of this part shall be subject to the following conditions:

(a) No essential or significant reduction in the quality or duration of the training and instruction shall be made by the grantee institution unless approved by the Director of the appropriate Institute upon recommendation by the national advisory council for such Institute.

(b) No substitution may be made for the program director named in the application as responsible for the training and instruction unless the substitute director is found by the Director of the appropriate Institute to have substantially equivalent qualifications with respect to providing the training and instruction for which the grant was awarded.

(c) The fiscal and other records of the institution that relate to the training and instruction for which the grant was awarded shall be available for audit or other reasonable inspection by representatives of the Public Health Service.

(d) Additional conditions consistent with the regulations in this part may be imposed by the Director of the appropriate Institute prior to the award of any training grant if he determines that such conditions are necessary to carry out the purposes of such grant.

§ 64.5 Additional conditions; institutional expenses.

Amounts awarded to enable institutions to defray the expenses of providing training and instruction shall be subject to the following conditions in addition to those set forth in § 64.4:

(a) The funds awarded may be expended solely for the training and instruction program set forth in the application for the grant and for such other related purposes as are determined by the Director of the appropriate Institute to be necessary to such program.

(b) No part of the funds awarded may be used for the purchase of land or for the construction of buildings.

(c) No funds may be used for indirect costs or overhead in excess of the rate generally applicable to training grants at the time of the award.

§ 64.6 Additional conditions; stipends.

Amounts awarded to enable institutions to pay stipends and allowances to individuals receiving advanced training shall be subject to the following conditions in addition to those set forth in § 64.4:

(a) No part of the funds requested for stipend payments may be used for any other purpose unless approved by the Director of the appropriate Institute.

(b) No part of the amount awarded may be used as remuneration for employment or for the performance of personal services by the individuals receiving the training and instruction.

(c) No amount may be paid by the institution to any individual who, by reason of age, physical or mental condition, or other relevant factor would not, in the reasonable judgment of the institution, be able to make use of the training and instruction.

(d) No amount may be paid by the institution to an individual who does not meet the minimum qualifications for the training and instruction as established by the institution, nor shall any amount be paid to any individual who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the institution.

§ 64.7 Payments; repayment of unexpended balances; unauthorized expenditures.

(a) Payments to an institution of amounts awarded under the regulations of this part may be made in advance and shall be in such amounts as are necessary in the judgment of the Director of the appropriate Institute to carry out the training program as set forth in the approved application of the institution or in any extension or renewal thereof. Any funds paid and found in the judgment of such Director to be not necessary for such purposes shall be returned to the United States.

(b) In the event any part of the amount paid an institution is found by the Director of the appropriate Institute to have been expended by the institution for purposes or by any methods contrary to the regulations of this part or contrary to any condition to the award, then such institution, upon being notified of such finding and in addition to any other requirement, shall pay an equal amount to the United States.

(c) Whenever the Director of the appropriate Institute shall find that the application or other documents on the basis of which a grant was awarded under the regulations of this part contain a material misrepresentation by or on behalf of the institution, or whenever he shall find that the institution has not, after a reasonable opportunity, corrected a substantial failure to comply with these regulations or with any condition to the award, he shall promptly notify the institution of such finding. Upon receipt of such notice, such institution, in addition to any other action required by law or these regulations, shall return to the United States immediately all funds not actually expended at the time of its receipt of such notice. If requested by the institution, any such findings may be reviewed by the Surgeon General whose decision shall be final.

§ 64.8 Appropriate Institute.

As used in this part "appropriate Institute" shall mean the National Cancer Institute for training grants in the field of cancer; the National Institute of Mental Health for training grants in the field of mental disorders; the National Heart Institute for training grants in the cardiovascular and related fields; the National Institute of Dental Research for training grants in the field of dental diseases and conditions; the National Institute of Allergy and Infectious Diseases for training grants in the field of allergy and infectious diseases; the National Institute of Arthritis and Metabolic Diseases for training grants in the field of arthritis and metabolic diseases; the National Institute of Neurological Diseases and Blindness for training grants in the field of neurological diseases, blindness, and other sensory disorders; and any other Institute established by the Surgeon General under section 431 of the Public Health Service Act, as amended, for training grants in the field of those diseases constituting the responsibility of such Institute; "Appropriate Institute" shall also mean, with respect to National Library of Medicine training grants, the National Library of Medicine.

[21 FR 9869, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

PART 64a—OBLIGATED SERVICE FOR MENTAL HEALTH TRAINEESHIPS

Sec.
64a.101 Purpose.
64a.102 To whom do these regulations apply?
64a.103 Definitions.
64a.104 What requirements are imposed upon grantees?
64a.105 What are the conditions of obligated service?

AUTHORITY: Sec. 803, Pub. L. 96-398, 94 Stat. 1607-1608 (42 U.S.C. 242a).

SOURCE: 46 FR 39979, Aug. 5, 1981, unless otherwise noted.

§ 64a.101 Purpose.

This part establishes requirements to implement the service payback obligation of individuals who receive clinical traineeships in pyschology, psychiatry, social work, or nursing (that are not of limited duration or experimental nature) under section 303 of the Public Health Service Act.

§ 64a.102 To whom do these regulations apply?

This part applies to any institution which receives a training grant under section 303 of the Public Health Service Act and to any individual who receives a stipend or other trainee allowances under such a grant for any period beginning on or after July 1, 1981, for clincial training in the field of psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature.

§ 64a.103 Definitions.

As used in this part:

"Act" means the Public Health Service Act as amended by Pub. L. 96-398.

"Clinical traineeship" means a stipend or other trainee allowances provided to an individual for clinical training in psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature, under a training grant authorized by section 303 of the Act.

"Community Mental Health Centers Act" means the Community Mental Health Centers Act (42 U.S.C. 2689 *et seq.*) other than Part D thereof.

"Experimental nature" refers to the training of undergraduates; the training of individuals in disciplines other than psychology, psychiatry, nursing, or social work; and any other training which the Secretary specifically designates as experimental in the notice of award for a training grant under section 303 of the Act.

"Limited duration" means a period that is equal to or less than 180 days, computed cumulatively over a two year period which begins on the first day of the clinical traineeship.

"Mental Health Systems Act" means the Mental Health Systems Act (42 U.S.C. 9401 *et seq.*).

"Nonprofit private entity" means an agency, organization, institution or other entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual and which does not hold or use its net earnings for that purpose.

"Other trainee allowances" means financial assistance for those costs not covered by stipends, such as tuition, fees, and trainee travel, which are directly associated with and necessary to the training of individuals receiving stipends and are incurred within the period of training.

"Secretary" means the Secretary of Health and Human Services or other official of the Department to whom the authority involved has been delegated.

"Stipend" means financial assistance to an individual that is intended to help meet that individual's subsistence expenses during training.

§ 64a.104 What requirements are imposed upon grantees?

Recipients of training grants under section 303 of the Act that provide a clinical traineeship to any individual must:

(a) Give each such individual written notice of the service payback and recovery requirements of this part at the time the individual becomes a candidate for the traineeship;

(b) Before awarding the clinical traineeship, obtain the individual's written assurance, as required by § 64a.105(a), that he or she will satisfy these requirements; and

(c) Provide the Secretary with written notice of the date on which the individual's traineeship is terminated.

§ 64a.105 What are the conditions of obligated service?

In order to receive a clinical traineeship an individual must comply with the following conditions:

(a) *Written assurance.* Prior to the award of a clinical traineeship, the individual must sign a written assurance (in such form and manner as the Secretary prescribes) that he or she will satisfy the requirements of this section.

(b) *Commencement and crediting of service.* (1) An individual must start the obligated service within twenty-four months after termination of the clinical traineeship and carry out the service on a continuous basis unless, as specified in paragraph (e) of this section, the individual has requested and had approved, respectively, an extension of the time for beginning the service, or a break in service.

(2) Following termination of the traineeship, the individual must annually provide (in such form and manner as the Secretary prescribes) a written report describing those previous years' activities which are related to service that fulfills the payback obligation. The Secretary will review this report and credit all service performed in those categories specified in paragraph (d) of this section toward the individual's payback obligation, except any service which is performed:

(i) Before termination of the individual's clinical traineeship; and

(ii) As part of any activity, such as course work, preparation of a dissertation or thesis, or practicum, which is needed to complete the training for which the individual received the traineeship.

(c) *Duration of obligation.* The period of service payback must equal the period of support under the clinical traineeship on a month for month basis.

(d) *Performance of the obligated service*—(1) *General requirements.* The obligated service must consist of the provision of service for which the individual was trained (in the training program for which the clinical traineeship was received) and must be performed on a full-time basis (not less than 30 hours per week averaged over the obligated service period).

(2) *Preferred service.* Except as provided under paragraph (d)(3) of this section, the individual must provide the obligated service in:

(i) A public inpatient mental institution;

(ii) Any entity which is receiving or has received a grant under the Mental Health Systems Act or the Community Mental Health Centers Act;

(iii) A psychiatric manpower shortage area designated by the Secretary under section 332 of the Public Health Service Act and 42 CFR Part 5;

(iv) Any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which 50 percent or more of those served are within one or more of the following groups: Racial or ethnic minorities (American Indian or Alaskan Native, Asian or Pacific Islander, Black, Hispanic), chronically mentally ill, mentally retarded, criminal or delinquent populations, rape victims, physically handicapped, abusers of alcohol, or persons addicted to drugs or other substances, children and adolescents, the elderly, poverty populations, migrants, members of the armed forces (or veterans if seen in a Federal facility), residents of areas other than those defined as urbanized by the Department of Commerce, or any other special populations, such as groups of refugees or disaster victims, which are specifically designated by the Secretary for this purpose.

(3) *Alternate service.* If the individual obtains the written approval of the Secretary, the individual may fulfill his or her obligation by:

(i) Serving in any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which not less than 25 percent of those served are within one or more of the underserved population groups listed in paragraph (d)(2)(iv) of this section. The individual must demonstrate a service commitment of more than 50 percent of his or her time to the targeted populations.

(ii) Teaching, conducting research, or conducting evaluation directed at improving alcohol, drug abuse or mental health services to one or more of the priority population groups listed in paragraph (d)(2)(iv) of this section, or working in a position which fosters the closer collaboration of health and alcohol, drug abuse or mental health services.

(3) Providing in a public or private nonprofit entity consultation, training and education, liaison, community support or other professional services for which the individual was trained when the individual's work is directed toward improving alcohol, drug abuse or mental health services to the priority populations listed in paragraph (d)(2)(iv) of this section.

(e) *Conditions for deferral or break in service, waiver, or cancellation.* (1) Upon receipt of a written request showing good cause therefor by the individual having a payback obligation, the Secretary may:

(i) Extend the period for beginning the obligated service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repayment under paragraph (g)(2) of this section, if it is determined that:

(A) An extension or break in service is necessary for the completion of training;

(B) Performance of the obligation must be delayed because a temporary disability makes present performance impossible; or

(C) Performance of the obligation must be delayed because present performance would involve a substantial hardship and failure to extend the period would be against equity and good conscience.

(ii) Waive, in whole or in part, the service payback and recovery requirements of this section if it is determined that fulfillment would be impossible because the individual is permanently and totally disabled.

(2) Upon receipt of written notice giving evidence of a conflicting obligation under section 752 or 753 of the Act or of an election to fulfill an obligation under section 472 of the Act prior to an obligation under this section, the Secretary will extend the period for beginning service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repayment under paragraph (g)(1), as appropriate.

(3) The service payback and recovery obligations of an individual will be cancelled upon the submission to the Secretary of a certificate of that individual's death or other evidence which the Secretary determines to be satisfactory.

(f) *Conflicting or multiple payback obligations.* In any case where the individual has, in addition to a payback obligation incurred under this section, an obligation to perform service under section 752 or 753 of the Act (because of receipt of a National Health Service Corps scholarship) or under section 472 of the Act (because of receipt of a National Research Service Award), or both, performance of the same activity may not be counted toward more than one of these obligations. In determining the order in which obligations must be fulfilled, obligations under section 752 or 753 take precedence over obligations incurred under this section. However, with respect to obligations under this section and 472, the individual may elect which obligation to fulfill first. Any individual who has an obligation under section 752 or 753 or makes an election to fulfill an obligation under section 472 prior to an obligation under this section, must give written notice to the Secretary as provided by paragraph (e)(3) of this section.

(g) *Recovery for failure to perform obligated service.* (1) If an individual fails to begin or complete the obligated service in accordance with the requirements of paragraphs (a) through (f) of this section, the United States is entitled to recover from that individual an amount equal to three times the cost of the clinical traineeship (including stipends and other trainee allowances) plus interest on that amount calculated for the total period of support at the maximum monthly legal rate in effect at the time and place of payment of the traineeship, multiplied, in any case in which the service that was required has been performed in part, by the percentage which the length of service that was not performed is of the length of the service that was required to be performed. The amount will be determined under the following formula:

$$A=3(\phi+mi\phi)\left(\frac{t-s}{t}\right)$$

where A is the amount the United States is entitled to recover, ϕ is the cost of the clinical traineeship (including stipends and other trainee allowances); m is the number of months of support under the clinical traineeship; i is the maximum monthly legal rate of interest in effect at the time and place of payment of the traineeship; t is the total number of months of the service obligation; and s is the number of months of the obligation that have been served.

(2) Unless the Secretary extends the repayment period as provided in paragraph (e) of this section, the individual shall pay to the United States the total amount which the United States is entitled to recover under paragraph (g)(1) within three years of the date that the individual failed to begin or complete the period of obligated service (including failing to comply with the applicable terms and conditions of an extension or break in service granted the individual) as determined by the Secretary. At the end of the three-year period or the period of extension any unpaid amount becomes a debt owed to the United States with interest accruing as provided by law.

PART 65—FEES FOR DIRECT TRAINING, CENTER FOR DISEASE CONTROL

Sec.

65.1 Applicability.
65.2 Establishment of fees.
65.3 Definitions.
65.4 Schedule of fees.
65.5 Application procedures.
65.6 Payment of procedures.
65.7 Refunds.
65.8 Waivers.

AUTHORITY: Sec. 501, 65 Stat. 290; 31 U.S.C. 483a.

SOURCE: 38 FR 28290, Oct. 12, 1973, unless otherwise noted.

§ 65.1 Applicability.

The provisions of this Part 65 are applicable to direct training other than direct training subject to the provisions of Subpart D of Part 80, Title 42, Code of Federal Regulations (training conducted by the National Institute for Occupational Safety and Health).

§ 65.2 Establishment of fees.

Except as otherwise provided in § 65.8 effective July 1, 1973, a fee shall be charged for all students receiving direct training conducted by the Center for Disease Control.

§ 65.3 Definitions.

(a) "CDC" means the Center for Disease Control.

(b) "Direct training" means all public health training conducted directly by CDC through courses for employees or representatives of State and local governmental agencies, other Federal agencies, international agencies, private industries, universities, other non-CDC agencies and organizations, and private individuals.

§ 65.4 Schedule of fees.

(a) Following are estimated fee ranges:

	Fees per student day
Classroom courses	$25-$75
Homestudy courses	6-15
Laboratory courses	35-100

(b) The fees specified in paragraph (a) of this section are based upon an analysis of the cost of previous courses and are, therefore, subject to revision. Fee ranges are given to indicate that fees may vary according to course design and facility location, i.e., whether a student attends a headquarters course or a field course. Up-to-date fee schedules for regular training courses will be available from the CDC headquarters offices and will be published in an addendum to the CDC Training Bulletin (available on request) and, when necessary, a general notice will be published in the FEDERAL REGISTER. The fee for special training efforts will be based upon the training requirements agreed upon between the requester and CDC.

§ 65.5 Application procedures.

Specific training information, including application procedures, may be obtained from CDC headquarters offices and the CDC Training Bulletin. Applications for enrollment in direct training courses shall be made on form HSM 319-A (CDC) and submitted to CDC. Requests by organizations for field courses and special training efforts should be made in writing to CDC at the following address:

Center For Disease Control
Attention: Training
Atlanta, Ga. 30333

§ 65.6 Payment of procedures.

Upon notification of acceptance in a direct training course, applicants shall submit payment of fees as follows:

(a) Federal agency applicants shall submit a letter identifying the agency and office to be billed, the agency order number, and any code number or other necessary billing information.

(b) State and local agency applicants shall provide similar billing information or submit check payable to the Center for Disease Control.

(c) All other applicants shall submit a check payable to the Center for Disease Control prior to the commencement of the course.

§ 65.7 Refunds.

Fees may be refunded in full provided (a) notice of withdrawal is received no later than 10 days before commencement of the training and (b) the withdrawal does not result in cancellation of a course because of insufficient funds to produce the training. Fees will be refunded when an application is not accepted, when a course is oversubscribed, or when a course is canceled.

§ 65.8 Waivers.

(a) CDC may waive the fee requirement when such waiver is judged to be in the public interest. Requests for waiver shall accompany completed applications for training or shall be submitted by organizations during arrangements for training. Waiver requests shall be submitted in writing and must include (1) an explanation of the relationship of the applicant's job to the training desired and (2) a justification for waiver of the fee, which explains how the training relates to the achievement of national goals of concern to CDC and why a waiver is needed.

PART 66—NATIONAL RESEARCH SERVICE AWARDS

Subpart A—Direct Awards

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Subpart B—Institutional Grants

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 472, 88 Stat. 342 (42 U.S.C. 289*l*-1).

SOURCE: 45 FR 1822, Jan. 8, 1980, unless otherwise noted.

Subpart A—Direct Awards

§ 66.101 Applicability.

The regulations in this subpart apply to National Research Service Awards made by the Secretary to individuals for research, and training to undertake research, under section 472(a)(1)(A) of the Public Health Service Act, as amended (42 U.S.C. 289*l*-1(a)(1)(A)).

§ 66.102 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Nonprofit" institution means a corporation or association in which no part of the net earnings inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Award" means a National Research Service Award under section 472 of the Act (42 U.S.C. 289*l*-1).

(e) "Residency" means post-graduate training for doctors of medicine, osteopathy, dentistry, optometry, and podiatry, nurses, and other individuals providing health care directly to patients, in which the majority of the time is spent in non-research clinical training.

(f) "National Health Service Corps" means the Corps referred to in section 331 of the Act (42 U.S.C. 254d).

(g) "Noncitizen national of the United States" means a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(h) "Predoctoral training" means training at the post-baccalaureate level in a program leading to the award of a doctor of philosophy or science, or equivalent degree. For purposes of Awards under the minority access to research careers programs of the National Institute of General Medical Sciences and the Alcohol, Drug Abuse, and Mental Health Administration, "predoctoral training" also means training in a program leading to the award of a baccalaureate degree in science or equivalent degree.

(i) "Postdoctoral training" means training of individuals holding a doctor of philosophy, science, medicine, dentistry, osteopathy, optometry, podiatry, veterinary medicine, engineering, nursing sciences, public health, or equivalent degree.

§ 66.103 Eligibility.

To be eligible for a National Research Service Award an individual must:

(a) Be a citizen, noncitizen national of the United States, or lawfully admitted to the United States for permanent residence at the time of application; and

(b) Propose to engage on a full-time basis in research, or training to undertake research, in a program specified in section 472(a)(1)(A) of the Act.

§ 66.104 Application.

(a) Application for an Award under this subpart shall be made on a form approved for that purpose by the Secretary. Applicants shall submit completed forms on or before the dates the Secretary may prescribe.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees;

(2) The subject area of the proposed research or training;

(3) The proposed period of Award;

(4) If the proposed period of Award would provide the individual with aggregate support in excess of five years at the predoctoral level or three years at the postdoctoral level, the justification for this request; and

(5) The availability of necessary resources facilities at the institution where the research or training would be conducted.

§ 66.105 Requirements.

The Secretary shall make an award to an individual under this subpart only if:

(a) For any Award made for a period in excess of three months, the individual has submitted to the Secretary a written assurance (in the form the Secretary may prescribe) that he or she will satisfy the requirements of § 66.110;

(b) If the proposed research or training would take place at an institution other than one operated by the Public Health Service agencies listed in section 472(a)(1)(A) of the Act, the institution has submitted a written assurance (in the form the Secretary may prescribe). The assurance shall indicate that:

(1) The applicant has been accepted to the institution for the purpose of engaging in the research or training for which an Award is being sought;

(2) The Award will not be used to support a residency; and

(3) In the event an Award is made, the institution will make available to the applicant any resources and facilities described in the application as necessary to carry out the research or training.

(c) Effective July 1, 1975, the proposed research or training is in a subject area for which there is a need for personnel, as determined under section 473 of the Act (42 U.S.C. 289*l*-2); and

(d) The individual has submitted a written assurance (in the form the Secretary may prescribe) that the Award will not be used to support a residency.

§ 66.106 Award.

(a) Within the limits of funds available, the Secretary shall make Awards to those applicants:

(1) Who have satisfied the requirements of § 66.105; and

(2) Whose proposed research or training would, in the judgment of the Secretary, best promote the purposes of section 472(a)(1)(A) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the particular proposal;

(ii) The availability of resources and facilities to carry it out;

(iii) The qualifications and experience of the applicant; and

(iv) The need for personnel in the subject area of the proposed research or training.

(b) All Awards shall be in writing. Each shall specify:

(1) The period of the Award;

(2) The total recommended stipends and allowances provided for the entire Award period;

(3) The amount awarded for the initial year of that period (see § 66.107); and

(4) The amount of the payments to the institution for the cost of services provided the awardee by the institution during the initial year of that period (see § 66.108).

(c) Neither the approval of any application nor any Award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other Award with respect to any approved application or portion thereof.

(d) No individual may receive an aggregate of more than five years of support at the predoctoral level and three years at the postdoctoral level unless the Secretary waives, for good cause shown, this limitation for the individual. In determining what constitutes "good cause," the Secretary shall take into account such factors as whether the applicant proposes to pursue a combined program leading to the degrees of doctor of medicine and doctor of philosophy.

§ 66.107 Payments to awardees.

(a) Individuals receiving Awards shall be entitled to the stipends and allowances the Secretary may designate, taking into account the cost of living, and such other factors as the needs of the program and the availability of funds.

(b) Payments of stipends and allowances shall, at the discretion of the Secretary, be made to the awardee or the sponsoring institution for payment to the awardee.

§ 66.108 Payments to institutions.

The institution shall be entitled to an allowance to help defray the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided to the individual by the institution. The Secretary shall determine the amount of payments based upon reasonable costs to the institution of establishing and maintaining the quality of research and training programs for which it receives support under this subpart. The Secretary may make payments to the institution either in advance or by way of reimbursement.

§ 66.109 Termination.

(a) The Secretary may terminate an Award prior to its normal expiration date:

(1) At the written request of the awardee; or

(2) If the Secretary finds that the awardee has materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made.

(b) In the event an Award is terminated, the Secretary shall notify the awardee in writing of this determination, the reasons for termination, the effective date, and any procedural rights available.

§ 66.110 Service, payback, and recovery requirements.

(a) Each individual who receives an Award made for a period in excess of three months shall upon completion of the Award engage for a period equal to the period of support in health research or teaching or, when in academic employment, any combination of research or teaching which is in accordance with the usual patterns of such employment.

(b) If the individual is a physician, dentist, nurse, or other individual trained to provide health care directly to individual patients, and if the Secretary determines that there are no suitable research or teaching positions available to the individual, and so authorizes the individual, the individual may:

(1) Serve as a member of the National Health Service Corps for a period equal to the period of support; or

(2) Provide services in his or her specialty for a health maintenance organization to which payments may be made under section 1876 of Title XVIII of the Social Security Act and which serves an underserved population (as defined in section 1302(7) of the Act) for a period equal to the period of support.

(c) If the individual is not trained to provide health care directly to individual patients, and if the Secretary determines that there are no suitable research or teaching positions available to the individual, and so authorizes the individual, the individual may engage in a health activity appropriate to his or her education and training for a period equal to the period of support.

(d) Except as provided in § 66.111, an individual subject to the requirements for service in paragraphs (a) through (c) of this section must begin to undertake the service on a continuous basis within two years after the termination of his or her Award.

(e) If the individual fails to undertake or perform the service in accordance with the requirements of paragraphs (a) through (d) of this section, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula:

$$A=\phi \frac{t-s}{t}$$

in which "A" is the amount the United States is entitled to recover; "ϕ" is the sum of the total amount paid under one or more Awards to the individual; "t" is total number of months in the individual's service obligation; and "s" is the number of months of the obligation served by him or her in accordance with paragraphs (a) through (c) of this section.

(f) Except as provided in § 66.111, the individual shall pay to the United States any amount which the United States is entitled to recover under paragraph (e) within a three-year period beginning on the date the United States becomes entitled to recover that amount. Interest shall accrue to the United States until any amount due the United States under paragraph (e) of this section is paid. The rate of interest will be fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to recovery.

§ 66.111 Suspension, waiver, and cancellation.

(a) The Secretary may extend the period for undertaking service prescribed in § 66.110(d), permit breaks in service under § 66.110(d), or extend the period for repayment under § 66.110(f) if the Secretary determines that:

(1) An extension or break in service is necessary so the individual may complete his or her research training;

(2) Completion during the period would be impossible because the individual is temporarily disabled; or

(3) Completion during the period would involve a substantial hardship to the individual and failure to extend the period would be against equity and good conscience.

(b) The Secretary may waive, in whole or in part, the obligation of the individual to repay pursuant to § 66.110(e) if the Secretary determines that:

(1) Fulfillment would be impossible because the individual is permanently and totally disabled; or

(2) Fulfillment would involve a substantial hardship to the individual and enforcement of the obligation would be against equity and good conscience.

(c) In making determinations under § 66.111(a)(3) and (b)(2), the Secretary will take into consideration such factors as:

(1) The individual's present financial resources and obligations;

(2) The individual's estimated future finanical resources and obligations;

(3) The reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(4) The extent to which the individual has been engaged in activities encompassed by §§ 66.110(a) through 66.110(c);

(5) Whether the individual has received sufficient training to be qualified to perform any such activities;

(6) The unavailability of employment opportunities appropriate to the individual's education and training; and

(7) Any other extenuating circumstances.

(d) Any obligation of any individual under this subpart will be cancelled upon the death of that individual.

[45 FR 1822, Jan. 8, 1980; 45 FR 9742, Feb. 13, 1980]

§ 66.112 Other HHS regulations and policies that apply.

Several other regulations and lolicies may apply to individuals and institutions receiving payments under this subpart. These include, but are not limited to:

45 CFR Part 46—Protection of human subjects.

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance.

45 CFR Part 91—Nondiscrimination on the basis of age in programs or activities receiving federal financial assistance.

43 FR 60108—Guidelines for Research Involving Recombinant DNA Molecules, published by the National Institutes of Health.

§ 66.113 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from an Award shall be subject to the conditions that all such materials shall bear appropriate acknowledgement of Department of Health and Human Services support and that the awardee shall furnish copies of these manuscripts or other materials as the Secretary may reasonably request.

§ 66.114 Copyright.

Where the work accomplished under an Award results in a book or other copyrightable material, the author is free to copyright the work, but the United States reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the Award.

§ 66.115 Inventions and discoveries.

(a) Any Award is subject to the regulations of the Department of Health and Human Services set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which Award funds are in fact used, whether within the scope of the Award as approved or otherwise. Each such invention or discovery shall be promptly and fully reported to the Assistant Secretary for Health, Department of Health and Human Services.

(b) Determination as to ownership and disposition of rights to such invention or discovery, including whether a patent application shall be filed, and, if so, the manner of obtaining, administering, and disposing of rights under any patent application or patent which may issue shall be made either:

(1) By the Assistant Secretary for Health, whose decision shall be final, or

(2) Where an Award is made to an individual for research or training at a non-Federal public or nonprofit private institution having a separate formal institutional patent agreement with the Department of Health and Human Services, by the institution in accordance with that agreement.

§ 66.116 Additional conditions.

The Secretary may with respect to any Award or class of Awards impose additional conditions prior to or at the time of any Award when in the Secretary's judgment such conditions are necessary to assure the carrying out of the purposes of the Award, the interests of the public health, or the conservation of funds awarded.

Subpart B—Institutional Grants

§ 66.201 Applicability.

The regulations in this subpart apply to grants under section 472 (a)(1)(B) of the Public Health Service Act, as amended (42 U.S.C. 289*l*-1(a)(1)(B)), to public institutions and to nonprofit private institutions to enable these institutions to make National Research Service Awards to individuals for research, and training to undertake research, in programs specified in section 472(a)(1)(B) of the Act.

§ 66.202 Definitions.

The definitions in § 66.102 of Subpart A of this part apply to this subpart.

§ 66.203 Eligibility.

To be eligible for a grant under this subpart, an applicant must be:

(a) A public or nonprofit private institution; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 66.204 Application.

(a) Application for a grant under this subpart shall be made on a form approved for that purpose by the Secretary. Applicants shall submit completed forms on or before the dates the Secretary may prescribe.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The subject area or areas in which the proposed research or training will be conducted;

(2) The resources and facilities available for use by recipients of Awards in carrying out this research or training;

(3) The names, qualifications, and experience of the program director and principal staff members who will be responsible for the proposed program;

(4) The criteria to be employed in selecting recipients of Awards;

(5) The estimated number of recipients of Awards under the grant;

(6) The proposed project period and a detailed budget and justification for the amount of grant funds requested; and

(7) Proposed methods for monitoring and evaluating the performance of individual recipients of Awards, as well as the overall program.

[45 FR 1822, Jan. 8, 1980; 45 FR 9742, Feb. 13, 1980]

§ 66.205 Requirements.

(a) No Award shall be made to an individual from a grant under this subpart unless:

(1) For any Award made for a period in excess of three months, the individual has submitted to the Secretary a written assurance (in the form the Secretary may prescribe) that he or she will satisfy the requirements of § 66.110 of Subpart A of this part;

(2) Effective July 1, 1975, any Award is for research or training in a subject area for which there is a need for personnel, as determined under section 473 of the Act (42 U.S.C. 289*l*-2);

(3) The individual is a citizen or noncitizen national of the United States or has been lawfully admitted to the United States for permanent residence at the time of application;

(4) The Award includes a provision for termination in the event the recipient is found by the institution to have materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made; and

(5) The Award is not to be used to support a residency.

(b) No Award shall be made to an individual under such grant which would provide that individual with aggregate support in excess of five years for predoctoral training and three years for postdoctoral training, unless the Secretary for good cause shown as provided in § 66.106(d) of Subpart A of this part, waives the application of the limitation with respect to that individual.

(c) The provisions of §§ 66.110 and 66.111 of Subpart A of this part constitute terms and conditions of any Award made from a grant under this subpart.

[45 FR 1822, Jan. 8, 1980; 45 FR 9742, Feb. 13, 1980]

§ 66.206 Grant awards.

(a) Within the limits of funds available, the Secretary shall award grants to those applicants:

(1) Whose applications have been reviewed and recommended for approval by the appropriate national advisory council or board;

(2) Who have satisfied the requirements of § 66.205; and

(3) Whose proposed programs would, in the judgment of the Secretary, best promote the purposes of section 472(a)(1)(B) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the proposed program;

(ii) The adequacy of the resources and facilities available to the applicant;

(iii) The qualifications and experience of the program director and principal staff members;

(iv) The degree of the need for personnel in the subject area or areas of the proposed research or training;

(v) The administrative and managerial capability of the applicant;

(vi) The reasonableness of the proposed budget in relation to the proposed program; and

(vii) The adequacy of the methods for monitoring and evaluating the performance of individual recipients and the overall program.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 66.207 Other HHS regulations and policies that apply.

Several other regulations and policies apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals process.

45 CFR Part 16—Department grant appeal process.

45 CFR Part 46—Protection of human subjects.

45 CFR Part 74—Administration of grants.

45 CFR Part 75—Informal grant appeals procedures (indirect cost rates, and other cost allocations).

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and procedure for hearings under Part 80.

45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance.

45 CFR Part 91—Nondiscrimination on the basis of age in programs or activities receiving federal financial assistance.

43 FR 60108 —Guidelines for research involving recombinant DNA molecules, published by the National Institutes of Health.

[45 FR 1822, Jan. 8, 1980; 45 FR 9742, Feb. 13, 1980]

§ 66.208 Additional conditions.

The Secretary, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 67—NATIONAL CENTER FOR HEALTH SERVICES RESEARCH GRANTS

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AUTHORITY:: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 305, 88 Stat. 363 (42 U.S.C. 242c).

SOURCE: 43 FR 34472, Aug. 4, 1978, unless otherwise noted.

Subpart A—Grants for Health Services Research, Evaluation, and Demonstration Projects

§ 67.10 Purpose and scope.

The regulations of this subpart are applicable to the award through the National Center for Health Services Research of grants under section 305(b) of the Public Health Service Act (42 U.S.C. 242c(b)) to support identified health services research, evaluation, or demonstration projects to investigate:

(a) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(b) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(c) The design, construction, utilization, organization, and cost of facilities and equipment.

§ 67.11 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act.

(b) "Budget period" means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.

(c) "Direct costs" means the costs that can be identified specifically with a particular cost objective, such as compensation of employees for the time and effort devoted specifically to the approved project, and the costs of materials acquired, consumed or expended specifically for the purpose of the approved project.

(d) "Grantee" means the public or nonprofit entity or individual that receives a grant under section 305(b) and this subpart for a health services research, evaluation or demonstration project and assumes legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

(e) "National Center for Health Services Research" means that unit of the Department of Health and Human Services established by section 305(a) of the Act.

(f) "Nonprofit" as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(g) "Project period" means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal Government to any additional, supplemental or continuation support beyond the current budget period.

(h) "Principal investigator" means a single individual, designated in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

(i) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(j) "Peer review group" means a panel of experts who are neither officers nor employees, other than by reason of their appointment, of the United States qualified by training and experience in particular scientific and technical fields to give expert advice, in accordance with the provisions of this subpart, on the scientific and technical merit of grant applications.

§ 67.12 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit entity and any individual is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 305(b) of the act and this subpart may be made to eligible applicants for the purpose of assisting in meeting the costs of health services research, evaluation, or demonstration projects as described in § 67.10; *Provided,* That no grant may be made under this subpart for any health services research, evaluation, or demonstration project for which a grant under another provision of the act (other than section 304) may be made.

§ 67.13 Application.

(a) An application for a grant under this subpart shall be submitted at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the act, the regulations of this subpart and any additional terms or conditions of any grant awarded.

(b) In addition to such other information as the Secretary may require, an application under this subpart must contain the following:

(1) A description of the problem in the area of health services that the project will address;

(2) A description of the hypotheses that will be tested or the specific objectives that will be served by the project as they relate to the general problem area;

(3) A description of the manner in which the project will be organized and managed;

(4) A specification of the data that will be collected or used in the project;

(5) A description of the analytic procedures that will be employed in the project;

(6) The names and qualifications of the principal investigator and principal members of the staff that will be assigned to the project and their roles;

(7) A description of the facilities and resources that will be available to the applicant, if any; and

(8) A complete and detailed budget and justification for the amount of grant funds being requested.

§ 67.14 Evaluation of applications.

(a) *Projects with direct costs over the project period in excess of $35,000.* (1) All applications for grant support under this subpart for a project with estimated direct costs over the project period in excess of $35,000 will be submitted by the Secretary for review to a peer review group whose members will be selected based upon their training and experience in relevant scientific and technical fields taking into account among other factors:

(i) The level of formal education (e.g., M.A., Ph. D., M.D.) completed by the individual;

(ii) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigators, assistant) in which the individual has done so, and the quality of such research;

(iii) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; and

(iv) The need of the peer review group to include within its membership experts from various areas of specialization within relevant scientific and technical fields.

(2) In carrying out a review under this paragraph the peer review group will take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the proposed project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) The peer review group to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted which shall contain the following parts:

(i) The first part shall consist of a factual summary of the proposed project, including a description of its purpose, scientific approach, location, total budget and manpower requirements.

(ii) The second part shall address the scientific and technical merit of the proposed project and shall consist of a critique of the proposed project with regard to the factors described in § 67.14(a)(2). This portion of the report shall include a set of recommendations to the Secretary with respect to the disposition of the application based upon its scientific and technical merit. The peer review panel may recommend that the Secretary approve, disapprove or defer a decision on the application in order to obtain further information. Where the peer review panel recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application. Where the peer review panel recommends approval, it shall also provide its recommendation regarding the appropriate project period and level of support for the proposed project.

(iii) The third part of the report shall describe the peer review panel's review of the importance of the problem that is to be addressed by the proposed project and its potential impact.

(b) *Project with direct costs over the project period of $35,000 or less.* (1) Applications for grant support under this subpart for a project with estimated direct costs over the project period of $35,000 or less (hereinafter sometimes referred to as "small grants") will be submitted by the Secretary for review to members of the staff of the National Center for Health Services Research and where desirable to assess the scientific merit of an application to at least two outside experts who are neither officers nor employees of the United States selected by the Director of the National Center for Health Services Research on the basis of their training and experience in particular scientific and technical fields, their knowledge of health services research and the application of research findings, and their special knowledge of the problem being addressed in the specific proposal.

(2) In carrying out a review under this paragraph, the reviewers will, take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) Each reviewer to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted. Each report shall summarize the reviewer's findings and provide recommendations with regard to approval, disapproval, or deferral of the application in order to obtain additional information.

§ 67.15 Disposition of applications.

On the basis of the Secretary's evaluation of the application as provided in § 67.16, the Secretary shall either (a) approve, (b) defer for a later decision, or (c) disapprove any application for grant assistance under this subpart: Disapproval of an application shall not preclude its reconsideration if the application is resubmitted in the same or a revised version at a later date.

§ 67.16 Grant award.

(a) *General.* (1) Within the limits of funds available for such purpose and subject to the limitation of section 308(c) of the act, the Secretary may award grants to those applicants whose approved projects will in his judgment best promote the purposes of section 305(b) of the act and the regulations of this subpart, taking into consideration:

(i) Recommendations made pursuant to § 67.14.

(ii) The appropriateness of the budget.

(iii) The extent to which the research proposal and the fiscal plan provide assurance that effective use will be made of grant funds.

(iv) The business management capability of the applicant.

(v) The competence and skill of the staff, especially the senior personnel, in light of the scope of the project.

(vi) The probable usefulness of the project results for dealing with national health care problems, policies, and programs.

(vii) The relative priority of the proposed project in light of the established priorities of the National Center for Health Services Research.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the project as proposed in the application including a different level of grant support from that requested in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the Notice of Grant Award.

(3) All grant awards shall be in writing. The Notice of Grant Award shall set forth the amount of funds awarded for the conduct of the approved project during the first budget period and the amount of annual support recommended for the remainder of the project period.

(4) The project for any grant under this subpart shall be specified in the Notice of Grant Award and shall begin no later than 9 months following the date of such award. In no case will a project be approved for a project period exceeding 5 years. Where the Secretary determines on the basis of a request by the grantee prior to the completion of the currently active grant that additional time is needed to permit the use of funds previously awarded but not expended, the approved project may be extended for a period of time not to exceed 12 months except that in no case may the project period exceed 5 years and 6 months. No additional support may be awarded for any portion of a project period in excess of 5 years.

(5) Neither the approval of any application nor the awarding of any grant shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the project or any part of the project. For continuation support, grantees must make separate application annually and at such times and in such form as the Secretary may prescribe.

(b) *Determination of grant amount.* (1) The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(i) On the basis of the estimate of the actual indirect costs reasonable related to the project; or

(ii) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) For particular categories of small grants, such as dissertation research support, the Secretary may establish a limit on direct costs that is less than $35,000 for the project period. Such limit will be announced in advance of the deadline for receipt of applications for such grants.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved project where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved project activities for that period, or that a supplemental award to fund incremental activities not initially approved for the period would substantially further the objectives of the project. The Secretary may also make a supplemental award where in his judgment such an award is necessary for the preparation of data in suitable form for transmittal in accordance with § 67.25. In cases where the award of any supplemental grant for a project exceeding $35,000 in direct costs would result in supplemental awards (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.25) during the project period in the aggregate exceeding twenty percent (20 percent) of the approved direct costs of the project, the Secretary will obtain the views of the peer review group which first evaluated the initial application prior to making any such award. The peer review group shall submit a written report to the Secretary which describes the current status of the project, the basis for the request and the potential consequences of any request where the recommendation is to disapprove. In the case of small grants, the Secretary will not approve any supplemental grant award during the project period (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.25) which will in the aggregate exceed ten percent (10 percent) of the direct costs of the project.

(d) *Noncompeting continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period of any previously approved project where the Secretary finds on the basis of such progress and accounting reports as may be required and after considering any recommendations made pursuant to this paragraph, that the project activities during the current budget period justify continued support of the project for an additional budget period. Each project with a project period in excess of 2 years and with direct costs over the project period in excess of $35,000 will be reviewed during the second budget period and during each subsequent budget period (except for the last budget period of the project period) by at least two members of the same peer group which reviewed the proposal in accordance with § 67.14. Such group shall review the application for continuation support and make recommendations to the Secretary concerning the disposition of such application based upon its evaluation of:

(1) The progress of the project in meeting project objectives,

(2) The appropriateness of the management of the project and allocation of resources within the project,

(3) The adequacy and appropriateness of the plan for the carrying out of the project during the budget period in light of the accomplishments during previous budget periods, and

(4) The reasonableness of the proposed budget for the subsequent budget period where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period.

§ 67.17 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project shall be carried out in accordance with the approved application.

(b) The principal investigator shall be responsible for the conduct of the project unless replaced by another individual found by the Secretary to be qualified to carry out such responsibilities. Where the principal investigator becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

§ 67.18 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved project. The amounts otherwise payable to any grantee shall be reduced by:

(a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request by the Secretary for the purpose of conducting the approved project; and

(b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such approved project, if such officer or employee was assigned or detailed by the Secretary at the request of the grantee to perform such services.

§ 67.19 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for carrying out the approved project in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles, prescribed in Subpart Q of 45 CFR Part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the approved project.

§ 67.20 Termination.

The termination of any grant under this subpart will be governed by the relevant provisions of Subpart M of 45 CFR Part 74 and the terms and conditions of the grant award. Where a grantee unilaterally terminates a portion of a grant, the Secretary may terminate such grant in whole where he determines that the remaining portion of the grant will not accomplish the purposes for which the grant was made.

§ 67.21 Nondiscrimination.

Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the ground of race, color, or national origin).

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 974) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(c) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(d) Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 67.22 Human subjects and animal welfare.

(a) No award may be made under this subpart unless the applicant has complied with 45 CFR Part 46 and other applicable requirements pertaining to the protection of human subjects.

(b) No award may be made under this subpart unless the applicant has complied with Chapter 1-43 of the Department of Health and Human Services Grants Administration Manual and any other requirements concerning animal welfare.

§ 67.23 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, the grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter, or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as practicable and in such form as to make such materials understandable.

§ 67.24 Confidentiality.

No information obtained by a grantee in the course of its health services research, evaluation, or demonstration activities may be used for any purpose other than the purpose for which it was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary may prescribe.

§ 67.25 Control of data.

Except as otherwise provided on the terms and conditions of the award and subject to the confidentiality requirements of § 67.24, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects supported under this subpart shall be made available to the Secretary upon request.

§ 67.26 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total or a selected element of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under grant shall be accounted for as follows:

(1) Royalties received during the period of grant support as a result of copyrights or patents shall be retained by the grantee and in accordance with the terms and conditions of the grant, be disposed of under either, or a combination of the following options:

(i) Used by the grantee for any purposes that further the objectives of the legislation under which the grant was made.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support shall be disposed of as follows:

(i) Patent royalties shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise, except State or local government grantees which receive royalties in excess of $200 a year shall return the Federal share of the excess amount (computed by applying the percentage of Federal participation in the cost of the grant supported project to the excess amount) to the Federal Government, unless specific agreement provides otherwise.

(c) *Grant closeout*—(1) *Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each approved project a full account, as provided herein, as of the termination of grant support which shall be at the end of the project period or the date of any termination of grant support pursuant to the applicable provisions of Subpart M of 45 CFR Part 74 and the terms and conditions of the grant award.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to the applicable provisions of 45 CFR Part 74 and the terms and conditions of the grant award. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the granteee or its successors or assignees by set-off or other action as provided by law.

§ 67.27 Applicability of 45 CFR Part 74.

The provision of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR PART 74

Subpart:
- A—General.
- B—Cash Depositories.
- C—Bonding and Insurance.
- D—Retention and Custodial Requirements for Records.
- F—Grant-Related Income.
- G—Matching and Cost Sharing.
- K—Grant Payment Requirements.
- L—Budget Revision Procedures.
- M—Grant Closeout, Suspension, and Termination.
- O—Property.
- Q—Cost Principles.

§ 67.28 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project or the conservation of grant funds.

Subpart B—Grants for Health Services Research Centers

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); sec. 305(d), as amended, 88 Stat. 364; (42 U.S.C. 242c(d)).

SOURCE: 41 FR 5226, Feb. 4, 1976, unless otherwise noted.

§ 67.101 Purpose and scope.

(a) The regulations of this subpart are applicable to the award of grants under section 305(d) of the Public Health Service Act, as amended, to assist in meeting the costs of planning, establishing and operating multidisciplinary Health Services Research Centers by providing support for both permanent staff composed of experts from different disciplines and the administrative costs of carrying out multidisciplinary health services research, evaluations and demonstrations respecting:

(1) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(2) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(3) The design, construction, utilization, and cost of facilities and equipment.

(b) Additional support awarded under this subpart, for National Special Emphasis Centers is intended to support staff, research, demonstration, and evaluation projects, training programs, and administrative costs for activities appropriate to the particular area of special emphasis.

§ 67.102 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(d) "Project period" means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal government to any additional, supplemental or continuation support beyond the current budget period.

(e) "Budget period" means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.

(f) "Center" means a Health Services Research Center supported under this subpart.

(g) "National Special Emphasis Center" mean a Center which directs a substantial portion of its efforts in research training, technical assistance, and other appropriate activities to a particular aspect of health care delivery specified by the Secretary and requiring a particular kind of scientific expertise. Such Centers shall include:

(1) A Health Care Technology Center, which shall focus on all forms of technology, including computers and electronic devices, and its applications in health care delivery;

(2) A Health Care Management Center, which shall focus on the improvement of administration and organization in the health field, the training and retraining of administrators of health care enterprises, and the development of leaders, planners and policy analysts in the health field; and

(3) Such other Centers as the Secretary shall deem appropriate, provided that formal notification of the competition for a grant award and designation as a National Special Emphasis Center under this subpart shall be made at least ninety (90) days prior to the closing date for filing applications for Center grants.

(h) "State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(i) "Grantee" means the public or nonprofit private entity that receives a grant under section 305(d) of the Act and this subpart and assumes legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

(j) "Director" means a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific, technical, and administrative direction of the Center.

§ 67.103 Eligibility.

Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart; *Provided*, That no entity is eligible for assistance for more than one Center at any one time.

§ 67.104 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such manner as the Secretary may prescribe.[1]

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart and the terms and conditions of any grant award.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A description of the manner in which the applicant intends to plan and establish a Center, including a timetable for making the proposed Center operational;

(2) A description of the staff of the proposed Center, including their qualifications, academic training, responsibilities and functions;

(3) A description of the manner in which the staff will be organized and supervised to carry out the proposed activities of the Center;

(4) A description of the applicant's plan for providing at the Center educational opportunities to students, health professionals and other appropriate individuals;

(5) A description of the applicant's plan for sharing the knowledge and expertise of the Center's staff by providing technical assistance to appropriate organizations and individuals and through other forms of public and community services;

(6) A description of the applicant's plan for disseminating the Center's research findings to appropriate forums;

(7) A description of the need of the region in which the proposed Center will be located for a Center and a description of the areas of research which the applicant expects the Center to address by virtue of particular problems and characteristics of the local health care delivery system;

(8) A description of the organizational structure of the applicant and the nature of any relationship with and access to health care delivery systems in which research activities can be undertaken and research findings tested;

(9) A description of the procedures by which research projects will be selected, including the methodology to be utilized in ensuring that such projects will be selected on the basis of (i) the regional or national importance of the problem to be addressed, (ii) the unique potential for definitive research on a problem, and (iii) opportunities for local application of the research findings;

(10) A budget which allocates the total support both by type of expenditure and by the activities identified in paragraphs (c) (1), (4), (5), (6), and (9) of this section;

(11) A description of the resources which the applicant plans to make available to the proposed Center;

(12) A description of the proposed Center's relationships with other academic institutions and research organizations with regard to the impact of such relationships on the quality and scope of the Center's research and the responsiveness of its project selection to local, regional and national priorities; and

(13) Assurances satisfactory to the Secretary that the Center will meet the operational requirements of § 67.107 when it becomes operational.

(d) In addition to the material specified in paragraph (c) of this section, an application for a grant with a designation as a National Special Emphasis Center shall also contain the following:

(1) A description of the areas of research which the applicant expects the Center to address by virtue of the particular problems and characteristics of the field of special emphasis;

(2) A description of the nature of any relationships with and access to health care delivery systems that would enhance the ability to carry out research, evaluations, and demonstra-

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[1] Applications and instructions are available from the Director, Review and Advisory Services, National Center for Health Services Research, Health Resources Administration, 5600 Fishers Lane, Rockville, Maryland 20852, Room 15-35.

tions in management, technology, or other areas of special emphasis;

(3) A description of the procedures by which special emphasis projects will be selected including the methodology to be utilized in ensuring that such projects will be selected on the basis of national importance of the problem being addressed and the unique potential for definitive research on a problem;

(4) A description of the resources which the applicant plans to make available to enhance the special emphasis activities;

(5) A description including a budget, of the proposed Center's plan for disseminating its research findings to groups and individuals particularly concerned with the area of special emphasis; and

(6) Assurances satisfactory to the Secretary that it will meet the additional operational requirements of § 67.107 when it becomes operational.

§ 67.105 Evaluation and disposition of applications.

(a) *Evaluation.* (1) All applications for a grant under this subpart will be submitted by the Secretary for review to a panel of experts who are neither officers or employees of the United States and who possess qualifications necessary to evaluate both the applicant's proposed method of planning, establishing and operating a Center and the potential of the proposed Center to make a valuable scientific contribution (hereinafter referred to as the review panel).

(2) The review panel to which an application has been submitted pursuant to paragraph (a)(1) of this section shall make a written report to the Secretary on each application so submitted. Each report shall consist of the following parts:

(i) The first part shall consist of a factual summary of the proposed Center, including a synopsis of the information required under § 67.104(c). If the applicant is applying for an award as a National Special Emphasis Center a factual summary of the information provided in accordance with § 67.104(d) shall also be submitted.

(ii) The second part shall address the scientific and technical merit of the application and shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the requirements of § 67.107.

(iii) The third part, where appropriate, shall address the scientific and technical merit of the application for an additional award for a National Special Emphasis Center. This part of the report shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the additional requirements of § 67.107.

(iv) The fourth part shall describe the panel's assessment of the relevance of the proposed program to regional or national health care issues.

(v) The fifth part shall consist of a set of recommendations to the Secretary with respect to the disposition of the application:

(A) The panel may recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for support as a Health Services Research Center. If the panel recommends approval, it shall also provide its recommendation regarding an appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(B) The panel may also recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for additional support as a National Special Emphasis Center. If the panel recommends approval, it shall also provide its recommendation regarding an appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(b) *Disposition.* On the basis of the Secretary's evaluation of the application and taking into consideration any recommendations made pursuant to paragraph (a) of this section, the Secretary shall either (1) approve, (2) defer for a later decision or (3) disapprove any application for grant assistance under this subpart. Such disapproval of an application shall not preclude its reconsideration if the application is resubmitted in the same or a revised version at a later date.

§ 67.106 Grant awards.

(a) *General.* (1) Within the limits of funds available for such purpose, the Secretary may award a grant to those applicants whose approved proposed Centers will in his judgment best promote the purposes of section 305(d) of the Act and this subpart, taking into consideration:

(i) Recommendations made pursuant to § 67.105.

(ii) The appropriateness of the proposed budget and the extent to which the fiscal plan provides assurance that effective use would be made of grant funds.

(iii) The capability of the applicant as demonstrated by organizational and institutional arrangements to successfully operate the proposed Center.

(iv) The qualifications, achievements, and commitment of the senior personnel.

(v) The strength and scientific integrity of the general program and approach of the proposed Center.

(vi) The nature of the sponsoring institution's commitment to the proposed Center and the relative importance it ascribes to the endeavor.

(vii) The past success and future potential of the proposed Center's personnel in receiving permanent and project related support from other sources.

(viii) The extent to which a proposed Center's planning process incorporates the concerns of pertinent constituents and reflects an awareness of significant research problems in health services.

(ix) The strength of the relationship the proposed Center has developed with components of a local health care system in which specific projects will be conducted and research findings tested.

(x) The integration of disciplinary interests within the proposed Center and the coordination of the research program with training and educational efforts.

However, no grant may be awarded which will result in more than twenty per centum (20%) of all Centers supported under this subpart being located in any one HHS region, except that this restriction shall not operate to proscribe awarding at least two grants under this subpart to institutions located in any single HHS region; *Provided,* That to the extent feasible, the Secretary will make such grants as will result in at least six Centers being operational in each fiscal year.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the Center as proposed in the application including a different level of grant support from that requested in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the grant award notice.

(3) All grant awards shall be in writing. The Notice of Grant Awarded shall set forth the amount of funds awarded for the conduct of the Center during the first budget period and the amount of support recommended for the remainder of the project period.

(4) The project period for any grant under this subpart shall be specified in the Notice of Grant Awarded and shall begin no later than nine months following the date of such award. In no case may a project period exceed five years; *Provided,* That the approved project period may be extended for a period not to exceed six months beyond five years where the Secretary determines on the basis of a request by the grantee prior to the termination of the currently active grant that such additional time is needed to permit the use of funds previously awarded but not expended. No additional support may be awarded for this period.

(5) Neither the approval of any application nor the awarding of any grant shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the Center or any part of the Center. For continuation support, grantees must make separate application annually and at such times and in

such form as the Secretary may prescribe.

(b) *Determination of grant amount.* The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the Center plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs.

Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved Center where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved Center activities for that period. The Secretary may also make a supplemental award where in his judgment such an award is necessary for the preparation of data in suitable form for transmittal in accordance with § 67.113. However, where the making of any supplemental award would result, in any budget period, in supplemental awards exceeding twenty per centum (20%) of the original award for direct Center costs in that budget period, the Secretary will prior to making such award obtain the recommendation of the review panel which evaluated the Center's initial application. The review panel shall submit a written report to the Secretary which describes the current status of the Center, the basis for the request, the panels recommendation concerning the request and the potential consequences of any request that is disapproved.

(d) *Non-competing continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved Center where the Secretary finds on the basis of such progress and accounting reports as may be required that the Center's activities during the current budget period justify continued support of the project for an additional budget period. Where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period. In addition, where he determines such support is necessary, the Secretary may provide financial support for the orderly phase-out of the supported activity.

§ 67.107 Operational requirements.

(a) Any Center supported under this subpart shall:

(1) Have a full-time Director who possesses a demonstrated capacity for sustained productivity and leadership in health services research, demonstrations, and evaluations. The Director shall oversee the research program and the general operation of the Center and shall to the extent practicable directly participate in research activities. Where the Director of a Center becomes unable to function in such capacity, the grantee shall so inform the Secretary as quickly as possible. Within five (5) days, the grantee shall designate an Interim Director and inform the Secretary of the name of such individual. Within ninety (90) days, the grantee shall nominate an Acting Director who, if approved by the Secretary, shall serve in that capacity until the end of the budget

period. The failure to obtain Secretarial approval of a new Director in the prescribed period of time shall result in immediate suspension of the grant;

(2) Have such additional full-time professional staff representing various disciplines relevant to health services research as necessary to plan, establish and operate the proposed Center and to carry out or administer research projects undertaken with the Center. The number and expertise of the staff shall be determined by the size of the proposed Center, the availability to it of staff resources other than its own immediate staff, and the nature and scope of the problems which its research will address:

(3) Be located within an established academic or research institution with available resources appropriate to the proposed activities to be conducted by the Center;

(4) Have written agreements with clinical settings which provide for settings appropriate for the initiation and evaluation of experiments in health services research;

(5) Select problems in health services for research, demonstrations and evaluations respecting:

(i) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(ii) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(iii) The design, construction, utilization, organization, and cost of facilities and equipment on the basis of (A) their regional or national importance, (B) the unique potential for definitive research on the problem, (C) the opportunities for local application of the research findings;

(6) Provide educational opportunities, through formal mechanisms, for university students, health professionals or other appropriate individuals;

(7) Provide for the dissemination of its research findings, subject to the requirements for confidentiality as set forth in section 308(d) of the Act and § 67.112;

(8) Provide, through a formal mechanism, for consultations and technical assistance to concerned individuals and groups of the geographical area in which the Center will be located.

(b) National Special Emphasis Centers shall, in addition to the requirements of paragraph (a) of this section:

(1) Provide for the dissemination of its research findings on a national scale to groups and individuals particularly concerned with the area of special inquiry;

(2) Select problems in its area of special emphasis for research, demonstration and evaluation on the basis of the national importance of the problem being addressed and the unique potential for definitive research;

(3) Provide, through a formal mechanism, for consultations and technical assistance appropriate to its area of special expertise to concerned individuals and groups on a national scale; and

(4) Employ all of the resources made available to the Center by virtue of its National Special Emphasis designation in planning, conducting and monitoring research, training, technical assistance, and other appropriate activities solely in its area of special emphasis.

§ 67.108 Grant payments.

The Secretary shall from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved Center. The amounts otherwise payable to any grantee shall be reduced by:

(a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request by the Secretary for the purpose of planning, establishing or operating the Center; and

(b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such Center, if such officer or employee was assigned or detailed by the Secretary at the request of the grantee to perform such services.

§ 67.109 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for planning, establishing or operating the approved Center in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the Center's approved activities.

§ 67.110 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on account of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing Title VI which applies to grants made under this subpart have been issued by the Secretary with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped person in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

(c) Grant funds used for remodeling, alteration or repairs shall be subject to the conditions that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 67.111 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, the grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as practicable and in such form as to make such materials understandable.

§ 67.112 Confidentiality.

No information obtained by a Center in the course of its health services research activities directly supported under this subpart may be used for any purpose other than the purpose for which it was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974 (Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary may prescribe. For purposes of this section and § 67.113, the term "directly supported", as it relates to health services research, demonstration, or evaluation projects, means discrete, identifiable projects supported under this subpart and not to solely the provision of administrative and staff support for the Center.

§ 67.113 Control of data.

Except as otherwise provided in the terms and conditions of the award and subject to the confidentiality requirements of § 67.112, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects directly supported under this subpart (as that term is defined in § 67.112) shall be made available to the Secretary upon request.

§ 67.114 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart; *Provided however,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(1) *State and local governments.* When the grantee is a State or local government as defined in 45 CFR 74.3, royalties shall be accounted for as provided in 45 CFR 74.44.

(2) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, royalties shall be accounted for as follows:

(i) Patent royalties, whether received during or after the project period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials; and any royalties in excess of the costs of publishing or producing such materials shall be distributed in accordance with Chapter 1-420 or the Department of Health and Human Services Grants Administration Manual.[2]

(c) *Grant closeout*—(1) *Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each Center a full account, as provided herein, as of the termination of grant support which shall be (i) the end of the project period, or (ii) the date of any termination of grant support pursuant to Subpart M of 45 CFR Part 74.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the grantee or its successors or assignees by set-off or other action as provided by law.

§ 67.115 Reports.

Each grant awarded under this subpart shall be subject to the condition that the grantee shall file written notification with the Secretary of each research, demonstration or evaluation project undertaken by the Center on the date that such project is initiated. Such notification shall include:

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[2] The Department of Health and Human Services Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

(a) A description of the project, including the hypotheses to be tested or the objectives to be pursued;

(b) The names of the principal investigators and the principal staff members that will be assigned to the project; and

(c) A budget, including an identification of the source of funds.

§ 67.116 Human subjects.

No award may be made under this Subpart unless the applicant has complied with 45 CFR Part 46 and other applicable requirements pertaining to the protection of human subjects.

§ 67.117 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR Part 74

Subpart:	
A	General.
B	Cash Depositories.
C	Bonding and Insurance.
D	Retention and Custodial Requirements for Records.
F	Grant-Related Income.
G	Matching and Cost Sharing.
K	Grant Payment Requirements.
L	Budget Revision Procedures.
M	Grant Closeout, Suspension, and Termination.
O	Property.
Q	Cost Principles.

§ 67.118 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved Center or the conservation of grant funds.

SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

PART 71—FOREIGN QUARANTINE

Subpart A—Definitions and General Provisions

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71.1 Definitions.
71.2 Periods of isolation and surveillance.
71.3 Periods of immunity.
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AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; secs. 361-369, 58 Stat. 703-706; 42 U.S.C. 264-272, E.O. 9708, 11 FR 3241, 3 CFR 1943-1948 Comp.; E.O. 10399, 17 FR 8648, 3 CFR, 1948-1953 Comp.; E.O. 10532, 19 FR 3209, 3 CFR, 1954-1958 Comp., unless otherwise noted.

SOURCE: 21 FR 9870, Dec. 12, 1956, unless otherwise noted.

NOTE: Information concerning forms called for in this part may be obtained from medical officers in charge of quarantine stations of the Public Health Service or from the Division of Foreign Quarantine, Washington D.C. Pertinent provisions of the International Sanitary Regulations (World Health Organization Regulations No. 2), which are referred to in this part are contained in § 71.700.

Subpart A—Definitions and General Provisions

§ 71.1 Definitions.

As used in this part, terms shall have the following meaning:

(a) *Certificate of vaccination.* Certificate of vaccination or revaccination against cholera, smallpox or yellow fever conforming with the rules and models prescribed by the International Sanitary Regulations.

(b) *Communicable disease.* An illness due to an infectious agent or its toxic products which is transmitted directly or indirectly to a well person from an affected person, animal, or arthropod (including insecta and arachnida) or through the agency of an intermediate host, vector or the inanimate environment.

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[1] The requirements of this subpart are in additional to and not in lieu of any other restrictions relating to the importation of nonhuman primates prescribed by the Fish and Wildlife Service, U.S. Department of the Interior (e.g., 50 CFR Parts 14, 17) and by other agencies of the Federal Government.

(c) *Contamination.* The presence of undesirable substance or material which may contain pathogenic microorganisms.

(d) *Day.* A period of 24 hours.

(e) *Deratting Certificate.* A certificate issued with respect to a vessel by the competent health authority for a port, in the form prescribed by the International Sanitary Regulations, recording the inspection and deratting of the vessel.

(f) *Deratting Exemption Certificate.* A certificate issued with respect to a vessel by the competent health authority for a port, in the form prescribed by the International Sanitary Regulations, recording the inspection and exemption from deratting of the vessel which has a negligible number of rodents on board.

(g) *Disinfection.* The act of rendering anything free from the causal agents of disease.

(h) *Disinfestation.* The act of destroying the vectors of a communicable disease.

(i) *Disinsecting.* The act of destroying insects or other arthropod vectors of a communicable disease.

(j) *Immunity.* The condition of being protected against a particular disease, either as a result of artificial immunization or through a previous attack of the disease in question.

(k) *Incubation period.* The period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestations of the disease.

(l) *Infected local area.* A local area (as defined in the International Sanitary Regulations) where:

(1) There is a nonimported case of cholera or smallpox; or

(2) There is a nonimported case of plague, or there is plague infection among rodents; or

(3) There is a nonimported case of yellow fever, or there is activity of yellow fever virus in vertebrates other than man; or

(4) There is an epidemic of typhus or relapsing fever.

(m) *Infected person.* Any person who is suffering from a quarantinable disease or who is considered by the medical officer in charge to be infected with such a disease.

(n) *Infestation.* The condition of harboring vectors.

(o) *International Sanitary Regulations.* The International Sanitary Regulations (World Health Organization Regulations No. 2) adopted by the Fourth World Health Assembly on May 25, 1951.

(p) *Infected vessel or aircraft.* See under particular quarantinable diseases in Subpart F of this part.

(q) *Isolation.* (1) When applied to a person or group of persons, the separation of that person or group of persons from other persons, except the health staff on duty, in such a manner as to prevent the spread of infection.

(2) When applied to animals, the separation of an animal or group of animals from other animals or vectors of disease in such manner as to prevent the spread of infection.

(r) *Medical officer in charge.* The medical officer of the Public Health Service responsible for the application of these regulations at a designated place or in a designated area.

(s) *Port under the control of the United States.* Any seaport or airport in the United States, its territories or possessions other than the Canal Zone.

(t) *Pratique.* A certificate issued by a quarantine officer releasing or provisionally releasing a vessel or aircraft from quarantine.

(u) *Quarantine.* The detention of a person, vessel, aircraft or other conveyance, animal or thing, in such place and for such period of time as may be specified in the regulations in this part.

(v) *Quarantine officer.* A medical officer or other specially trained employee assigned to quarantine duty by the Surgeon General.

(w) *Quarantinable diseases.* The specific communicable diseases: cholera, plague, smallpox, and yellow fever.

(x) *Relapsing fever.* Louse-borne relapsing fever.

(y) *Rodents.* Gnawing mammals capable of transmitting or harboring quarantinable diseases.

(z) *Surgeon General.* The Surgeon General of the Public Health Service.

(aa) *Surveillance.* The temporary supervision of a person who has been released from quarantine by the medical officer in charge upon the condition that he will submit himself to further medical examination or inquiry as required.

(bb) *Suspect.* A person who is considered by the medical officer in charge as having been exposed to infection by a quarantinable disease and to be capable of spreading that disease.

(cc) *Suspected vessel or aircraft.* See under particular quarantinable diseases in Subpart F of this part.

(dd) *Typhus.* Louse-borne typhus.

(ee) *Valid.* (1) With respect to a Deratting Certificate or Deratting Exemption Certificate issued for a vessel, a certificate issued by the competent health authority for a port not more than 6 months before presentation of the Certificate to the quarantine officer, or if the vessel is proceeding to a port designated or approved for the issuance of such Certificates, not more than 7 months before such presentation.

(2) With respect to a certificate of vaccination, a certificate presented within the applicable period of immunity prescribed in § 71.3.

(ff) *Vector.* An animal (including insects), plant, or thing which conveys or is capable of conveying pathogenic organisms from a person or animal to another person or animal.

(gg) *Yellow fever receptive area.* An area where the yellow fever virus does not exist but where Aedes aegypti or any other domiciliary or peri-domiciliary vector of yellow fever is present and development of the disease, if introduced, would thus be possible.

[22 FR 6461, Aug. 13, 1957, as amended at 38 FR 16861, June 27, 1973]

§ 71.2 Periods of isolation and surveillance.

Except as otherwise provided with respect to infected persons, where isolation or surveillance is authorized in this part the period of such isolation or surveillance shall be reckoned as hereinafter provided and shall not exceed the following appropriate incubation period of the quarantinable diseases:

(a) Plague: 6 days.

(b) Cholera: 5 days.

(c) Yellow fever: 6 days.

(d) Smallpox: 14 days.

(e) Typhus: 14 days.

(f) Relapsing fever: 8 days.

§ 71.3 Periods of immunity.

The following shall be the recognized period of immunity after successful immunization; in the case of yellow fever, the vaccine must be approved by the World Health Organization:

Cholera: 6 months, beginning 6 days after the first injection of the vaccine and on date of a revaccination during such period of 6 months.

Smallpox: 3 years, beginning 8 days after successful primary vaccination and immediately on revaccination.

Yellow fever: 6 years, beginning 10 days after date of original vaccination and from date of a revaccination within such period of 6 years.

§ 71.4 Compliance with conditions of surveillance.

(a) Every person who is placed under surveillance in accordance with the provisions of this part shall, during the period of surveillance:

(1) Give such information relative to his health and his intended destination and report to designated physicians or medical officers at such times for such medical examinations as may be required;

(2) Upon arrival at any address other than that stated as his intended destination when placed under surveillance, report his address to the medical officer in charge at the port or place of his entry.

(b) A person under surveillance shall, prior to departure from the United States, inform the medical officer in charge at the port or place of his entry, or departure, and such officer shall immediately notify the health authority of the place to which the person is proceeding.

§ 71.5 Departing persons, things, vessels or aircraft.

(a) If the medical officer in charge has reason to believe that a person proposing to depart from the United States by any means is infected with or has been exposed to infection by a quarantinable disease, he shall so advise the person and notify the local health authorities and the master or commander or person in charge of the vessel, aircraft or other conveyance on which the person proposes to depart.

(b) If the medical officer in charge has reason to believe that a departing vessel, aircraft or land conveyance has or may have on board possible agents of infection or vectors of a quarantinable disease, he shall notify the master, commander, or person in charge and offer to have performed such disinsecting, disinfection, or other measures as are necessary. He shall, if he considers that a risk of infection exists on board at the time of departure, notify all persons proposing to embark upon such ship, aircraft or conveyance and the health authorities at the next port of call or destination of the conditions aboard such vessel, aircraft or conveyance.

§ 71.6 Sanitary measures previously applied.

Any sanitary measure, other than medical examination, which has been applied prior to the arrival of a vessel or aircraft with respect to the quarantinable diseases shall not be repeated unless:

(a) After the departure of a vessel or aircraft from the port or airport where the measures were applied there is or has been on board an infected person or suspect, or there has occurred any other incident of epidemiological significance either in that port or airport or on board the vessel or aircraft which, in the judgment of the medical officer in charge, requires further application of any such measure, or

(b) The medical officer in charge has ascertained on the basis of definite evidence that the individual measure so applied was not substantially effective.

§ 71.7 Certificate of measures applied.

(a) The medical officer in charge shall, upon request, issue free of charge to a carrier a certificate specifying the sanitary measures applied to a vessel, an aircraft or a land conveyance, the parts thereof treated, the methods employed, and the reasons why the measures were applied. In the case of an aircraft this information shall on request be entered instead in the General Declaration.

(b) The medical officer in charge shall, upon request, issue free of charge:

(1) To any traveler a certificate specifying the date of his arrival or departure and the sanitary measures applied to him and his baggage;

(2) To the consignor, the consignee, or the carrier, or their respective agents, a certificate specifying the sanitary measures applied to any goods.

§ 71.8 Designation of vaccinating centers; authenticating stamps.

(a) Yellow fever vaccinating centers, authorized to issue certificates of vaccination against yellow fever, are designated by the Surgeon General. Such designation is made upon application therefor and the presentation of evidence satisfactory to the Surgeon General that a substantial need for the designation exists in the area to be served by the applicant and that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent and pure yellow fever vaccine.

(b) A designated yellow fever vaccinating center shall comply with instructions issued by the Surgeon General or by a delegated officer or employee of the Service for the handling, storage and administration of yellow fever vaccine. If a designated center fails to comply with such instructions, the Surgeon General may, after notice to the center, revoke such designation.

(c) International certificates of vaccination against yellow fever issued by Public Health Service facilities or Department of Defense medical facilities shall be authenticated by the official stamp or seal of such vaccinating centers. All other designated centers shall authenticate such certificates with a stamp of a design and size approved by the Surgeon General.

(d) International certificates of vaccination against smallpox and cholera issued for vaccinations performed in the United States shall be authenticated by:

(1) The stamp or seal of the Public Health Service, of the Department of Defense, or of the State or local health department of the area in which the vaccinating physician practices; or

(2) The stamp approved under paragraph (c) of this section for a yellow fever vaccinating center; or

(3) A stamp issued by the Public Health Service for such purpose.

§ 71.9 Listing of infected and receptive areas.

Each medical officer in charge shall maintain an accurate listing of (a) ports and other areas infected with quarantinable or other communicable diseases, and (b) yellow fever receptive areas.

[22 FR 6461, Aug. 13, 1957]

Subpart B—Measures at Foreign Ports

§ 71.11 Bills of health.

A vessel or aircraft at any foreign port clearing or departing for any port under the control of the United States shall not be required to obtain or deliver a bill of health.

§ 71.12 Measures prescribed by local health authority: Vessels and aircraft.

A vessel or aircraft at any foreign port or airport clearing or departing for any airport clearing or departing for any port under the control of the United States shall comply with sanitary measures prescribed by the health authority for such foreign port or airport in accordance with responsibility imposed by the International Sanitary Regulations to prevent the departure of infected persons or the introduction on board the vessel or aircraft of possible agents of infection or vectors of a quarantinable disease.

Subpart C—Notice of Communicable Disease Prior to Arrival

§ 71.31 Radio report of death or illness.

(a) *Vessels.* The master of a vessel destined for a port under the control of the United States shall report immediately, by radio, to the quarantine station at or nearest the port at which the vessel will arrive, the occurrence on board, among passengers or crew (including those who have disembarked or have been removed), during the 15-day period preceding the date of expected arrival or during the period since departure from a port under the control of the United States (whichever period of time is shorter), any death, without regard to cause or signs and symptoms, or any illness characterized by signs and symptoms as follows:

(1) Temperature of 100 F. (38 C.) or greater (i) which was accompanied or followed by rash, jaundice, or glandular swelling, or (ii) which persisted for 2 days or more; or

(2) Diarrhea severe enough to interfere with work or normal activity.

(b) *Aircraft.* The commander of an aircraft destined for an airport under the control of the United States shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive the occurrence, on board, among passengers or crew, of every death or illness as specified in paragraph (a) of this section.

[38 FR 16861, June 27, 1973, as amended at 38 FR 19222, July 19, 1973]

Subpart D—Vessels and Aircraft Subject to Quarantine Inspection

§ 71.46 General provisions.

(a) Upon arrival at a port under the control of the United States, a vessel or aircraft shall undergo quarantine inspection unless:

(1) The last port prior to such arrival was in an area determined by the Director, Center for Disease Control, to present no significant threat of introduction of communicable disease

into the United States or its possession;[1] or,

(2) A period of more than 15 days has elapsed since departure from the last port, or,

(3) The Director, Center for Disease Control, determines that exemption from quarantine inspection will present no significant threat of introduction of communicable disease into the United States or its possessions.

(b) Notwithstanding the provisions of paragraph (a) of this section:

(1) Vessels and aircraft shall comply with any conditions and carry out any additional measures specified in the pratique.

(2) A vessel shall undergo quarantine inspection prior to entry into such port if, within the 15-day period preceding such arrival, or during the period since departure from a port under the control of the United States, whichever period of time is shorter, there is or has been any death or illness among the passengers or crew, including those who have disembarked or been removed, as specified in § 71.31(a).

(3) An aircraft shall undergo quarantine inspection if there is or has been on board during the flight any death or illness among the passengers or crew, as specified in § 71.31(a).

(4) Vessels and aircraft shall undergo quarantine inspection if the Director, Center for Disease Control, determines that entry would be likely to cause the introduction of communicable disease.

[38 FR 16861, June 27, 1973]

§ 71.47 Vessels and aircraft of armed services.

(a) Vessels and aircraft belonging to or operated by the Armed Services of the United States may be exempted from quarantine inspection if the medical officer in charge is satisfied that they have complied with regulations of such armed services meeting the requirements of the regulations in this part. (For applicable regulations of the Armed Forces see Army Regulations No. 40-12; Navy General Order No. 20; Air Force Regulation No. 161-4.)

(b) Vessels belonging to or operated by the armed services of any foreign nation may, in the discretion of the medical officer in charge, be exempted from quarantine inspection if a commissioned medical officer of such service certifies that:

(1) Any person on board who is infected or suspected of being infected with a communicable disease will be isolated until it is determined whether or not he is infected with a quarantinable disease, and that

(2) The vessel is from a port where at the time of departure there was not present or suspected of being present cholera, plague, relapsing fever, smallpox, typhus, or yellow fever. When it is determined that any person on board such vessel is infected with a quarantinable disease, the vessel and its entire personnel shall be subject to the provisions of Subpart F of this part.

(c) Notwithstanding the exemption from quarantine inspection of a vessel or aircraft under this section, animals or articles aboard shall be required to comply with the applicable requirements of Subpart J of this part.

(E.O. 11070, 27 FR 12393, 3 CFR, 1959-1963 Comp.)

[21 FR 9870, Dec. 12, 1956, as amended at 28 FR 5299, May 29, 1963]

§ 71.48 Exempt vessels and aircraft subject to sanitary regulations.

A vessel or aircraft which has been exempted from quarantine inspection under § 71.46 or § 71.47 shall nevertheless be subject to the provisions of Subpart G of this part.

§ 71.49 Report of disease or rodent mortality on vessel during stay in port.

The master of any vessel calling at a port under the control of the United States shall promptly report to the medical officer in charge the occurrence of the following on the vessel during its stay in port:

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[1] A list of such areas and changes thereto will be published in the FEDERAL REGISTER. A current list may be obtained from the Director, Center for Disease Control, 1600 Clifton Road NE., Atlanta, Ga. 30333, Attention: Chief, Quarantine Branch; or from Public Health Service quarantine stations at United States ports.

(a) Any death or illness as specified in § 71.31(a).

(b) Unusual mortality or evidence of disease among rodents.

[21 FR 9870, Dec. 12, 1956, as amended at 38 FR 16862, June 27, 1973]

Subpart E—General Requirements Upon Arrival at Ports Under Control of the United States

§ 71.61 Applicability.

The measures prescribed in this subpart shall be taken with respect to vessels or aircraft which are subject to quarantine inspection pursuant to Subpart D of this part, and with respect to persons and things arriving on such vessels or aircraft.

§ 71.62 General provisions: Vessels and aircraft; permission for aircraft to discharge persons and cargo.

(a) *Vessels.* (1) The vessel shall fly a yellow flag. It shall anchor in the quarantine anchorage and await inspection, except as provided in paragraph (a)(2) of this section.

(2) If the medical officer in charge is of the opinion that proceeding to a designated point would not be likely to cause the introduction of communicable disease, he may direct the vessel to proceed to such a point to await inspection. He shall prescribe necessary measures to ensure that there is no movement of any person or thing onto or from the vessel without his permission, pending quarantine inspection.

(b) *Aircraft.* When an aircraft subject to quarantine inspection in accordance with this part arrives at the place of first landing (see § 71.502) the aircraft commander shall be responsible for the detention of the aircraft, its crew and passengers until they are released by the quarantine officer at the place of first landing. Any baggage, cargo, or other contents on board the aircraft shall be held at such place until released by the quarantine officer. (For procedure in case of emergency or forced landing, see § 71.504.)

§ 71.63 Persons: Restrictions on boarding and leaving vessels or aircraft, or having contact with persons aboard.

(a) *Vessels.* Except with the permission of the quarantine officer, no person other than the pilot shall board or be permitted to board any vessel subject to quarantine inspection until after it has been inspected by the quarantine officer and granted pratique. A person boarding such vessel shall be subject to the same restrictions as those imposed on the persons on the vessel. No person shall leave or be permitted to leave any vessel subject to quarantine inspection until after it has been inspected by the quarantine officer and granted pratique, except with the permission of the quarantine officer.

(b) *Aircraft.* Except with the permission of the quarantine officer, no person shall board or be permitted to board any aircraft subject to quarantine inspection or have contact with the crew or passengers of such aircraft until quarantine inspection of the aircraft, crew, and passengers has been completed. The same restrictions as those imposed on the crew and passengers shall be imposed on a person boarding such aircraft and on a person having contact with a passenger or member of the crew when the quarantine officer considers such contact a possible means of spreading a quarantinable disease.

§ 71.64 Maritime quarantine declaration.

(a) On arrival of a vessel, the master shall complete a maritime quarantine declaration on the Public Health Service Quarantine Declaration form. The completed form shall be delivered to the medical officer in charge or to the quarantine officer at the time quarantine inspection is begun. The declaration shall also be signed by the ship's surgeon if one is carried.

(b) The master of a vessel and the ship's surgeon, if one is carried, shall furnish all information as to health conditions on board during the voyage which may be required by the quarantine officer or medical officer in charge and shall comply with the regulations in this part and with any directions or requirements of the medical officer in charge pursuant to the regulations in this part.

§ 71.65 Aircraft declaration and manifest.

(a) When an aircraft is carrying passengers for hire or commercial cargo, the aircraft commander or any other authorized agent of the owner or operator of the aircraft shall deliver a general declaration to the quarantine officer immediately upon the first landing in the United States. Such declaration shall be on a form approved by the Surgeon General and the Commissioner of Customs, and shall include a report showing:

(1) Details of any illness suspected of being of an infectious nature that has occurred aboard the aircraft during the flight;

(2) Details of any other condition on board the aircraft during its flight which may lead to the spread of disease;

(3) Details of each disinsecting or sanitary treatment (place, date, time, method) during the flight (if no disinsecting has been carried out during the flight give details of most recent disinsecting);

(4) Any animals (including birds and insects), and cultures of bacteria, fungi, and viruses, and other infectious agents on board;

(5) Such other information and statements as are indicated on the general declaration form.

(b) Unless the aircraft is arriving directly on a trip that originated in Canada, there shall be delivered with the general declaration a passenger manifest showing the surname, given name, and middle initial of each arriving passenger.

§ 71.66 Quarantine inspection and controls.

(a) Quarantine inspection of a vessel or aircraft shall include:

(1) Inspection of the vessel or aircraft, its cargo, manifests, and other papers to ascertain the sanitary history and condition of the vessel or aircraft;

(2) Examination of the persons aboard the vessel or aircraft, their personal effects and records to determine the presence, or risk of introduction, of quarantinable and other communicable diseases.

(b) The medical officer in charge may require a vessel or aircraft to remain under quarantine controls until the completion of the measures authorized in this part which in his judgment are necessary to prevent the introduction or spread of a quarantinable or other communicable disease.

§ 71.67 Persons: Examination.

All persons on board shall be examined, except that on an approved regular line vessel or aircraft which carries a ship or flight surgeon, such examination may be limited to persons designated by the medical officer in charge.

§ 71.68 Vessels and aircraft: Persons and things: communicable diseases other than quarantinable diseases.

(a) Whenever the medical officer in charge has reason to believe that any arriving vessel or aircraft, or article or thing aboard, is or may be infected or contaminated with any of the communicable diseases listed in paragraph (c) of this section, he may disinsect, disinfect, disinfest, fumigate and take such other related measures respecting such vessel, aircraft, or article or thing aboard, or any part thereof, as he considers necessary to prevent the introduction, transmission, or spread of such communicable diseases.

(b) Whenever the medical officer in charge has reason to believe that any arriving person is suffering or has been exposed to infection from any of the communicable diseases listed in paragraph (c) of this section, he may place such person in isolation or under surveillance and may disinfect or disinfest his person, clothing or baggage as he considers necessary to prevent the introduction, transmission or spread of such communicable diseases.

(c) The communicable disease authorizing the application of sanitary and quarantine measures under paragraphs (a) and (b) of this section are: Anthrax, chancroid, chickenpox, dengue, diphtheria, favus, gonorrhea, granuloma inguinale, hemolytic streptococcal infections, infectious encephalitis, leprosy, lymphogranuloma venereum, meningococcus meningitis, poliomyelitis, psittacosis, ringworm of the scalp, syphilis, trachoma, tuberculosis, typhoid fever.

(E.O. 11070, 27 FR 12393, 3 CFR, 1959-1963 Comp.)

[21 FR 9870, Dec. 12, 1956, as amended at 28 FR 5299, May 29, 1963]

§ 71.69 Persons: Isolation.

Persons held under isolation pursuant to the provisions of this subpart and Subpart F of this part may be so held at facilities of the Public Health Service or, if such facilities are not available, on ships in quarantine pending other suitable arrangements for isolation and treatment. Such arrangements shall be made as soon as practicable.

§ 71.70 Persons: Isolation substituted for surveillance.

The medical officer in charge may require isolation where surveillance is authorized in this part whenever he considers the risk of transmission of infection by a suspect to be exceptionally serious.

§ 71.71 Restriction on movement of articles.

Articles from a vessel or aircraft shall not be carried into the place of detention except by permission of the medical officer in charge.

§ 71.72 Disinfection of imports.

When the freight manifest of a vessel or aircraft lists articles which may require disinfection under the provisions of this part, the medical officer in charge shall disinfect them on board or request the collector of customs to keep the articles separated from the other freight pending appropriate disposition.

§ 71.73 Exemption for mails.

Except to the extent that mail contains any of the foods or beverages referred to in § 71.82(d) which the medical officer in charge has reason to believe comes from a cholera infected local area, or any article or thing subject to quarantine restrictions under Subpart J of this part, nothing in the regulations in this part shall render liable to detention, disinfection or destruction any mail conveyed under the authority of the postal administration of the United States or of any other Government.

Subpart F—Particular Requirements Upon Arrival at Ports Under Control of United States

§ 71.81 Applicability.

In addition to the requirements of Subpart E of this part, the particular requirements prescribed in this subpart (affecting persons, vessels or aircraft, animals, and other imports) shall be observed with respect to vessels or aircraft which are subject to quarantine inspection under Subpart D of this part.

§ 71.82 Cholera: Vessels and aircraft; things.

(a) For the purpose of applying sanitary and quarantine measures against the spread of cholera:

(1) An infected vessel means a vessel which has on board on arrival a case of cholera or on which a case of cholera has occurred within 5 days prior to arrival.

(2) An infected aircraft means an aircraft which has a case of cholera aboard on arrival.

(3) A suspected vessel means a vessel which has had on board during the voyage a case of cholera more than 5 days prior to arrival.

(4) A suspected aircraft means an aircraft which has had on board during the voyage a case of cholera which has previously disembarked.

(b) An infected or suspected vessel or aircraft shall be detained in quarantine as may be necessary for the effective accomplishment of the applicable sanitary measures prescribed in this subpart.

(c) Personal effects and baggage of any infected person or suspect and any part of the infected or suspected vessel or aircraft considered to be contaminated shall be disinfected. Bedding or linen, human dejecta, bilge water, waste matter or water, and any matter considered to be contaminated shall not be unloaded or discharged until it has been disinfected.

(d) On arrival of an infected or suspected vessel or aircraft, or a vessel or aircraft arriving from an infected local area, the medical officer in charge may prohibit the unloading of, or may remove all fish, shellfish, fruit or vegetables to be consumed, uncooked, or beverages, unless such food or beverages are in sealed containers and the medical officer in charge has no reason to believe that they are contaminated. If any such food or beverage is removed it shall be safely disposed of. If any of said food or beverage forms part of the cargo in a hold of a vessel or freight compartment of an aircraft, the medical officer in charge at the port or airport at which such cargo is to be unloaded shall arrange for its safe disposal. Such other special precautions shall be taken as may be necessary to prevent contamination of food or water supplies of the vessel or aircraft.

(e) If the medical officer in charge considers the water supply of a cholera infected or suspected vessel or aircraft to be contaminated, he shall require the disinfection and removal of any water carried on board and if necessary the disinfection of the water system and of the water containers.

§ 71.83 Cholera: Vessels and aircraft; persons.

(a) Persons ill from cholera shall be removed and isolated until no longer infectious.

(b) On arrival of an infected vessel or aircraft the medical officer in charge may place under surveillance any person disembarking who produces a valid certificate of vaccination against cholera and may isolate all others disembarking. Such surveillance or isolation shall be reckoned from the date of disembarkation.

(c) On arrival of a suspected vessel or aircraft the medical officer in charge may place under surveillance any person disembarking. Such surveillance shall be reckoned from the date of arrival.

(d) Any person who, within 5 days prior to arrival, has departed from a cholera infected local area or arrives on a healthy vessel or aircraft which has departed from such an area within such time may be placed under surveillance if he has a valid certificate of vaccination against cholera or may be placed in isolation if he does not have such a certificate. The period of isolation or surveillance shall be reckoned from the date of departure of the person, or the vessel or aircraft, from the infected area.

(e) Any person who has departed from an infected local area within 5 days prior to arrival and who has symptoms indicative of cholera may be required to submit to a stool examination.

§ 71.84 Plague: Vessels and aircraft.

(a) For the purpose of applying sanitary and quarantine measures against the spread of plague:

(1) An infected vessel or aircraft means a vessel or aircraft which has on board on arrival a case of human plague, or a plague infected rodent. A vessel shall also be regarded as infected if a case of plague develops on board in a person more than 6 days after his embarkation.

(2) A suspected vessel means (i) a vessel which, not having a case of human plague on board on arrival, has had on board such a case developed by the person within 6 days of his embarkation or (ii) a vessel on which there is evidence of abnormal mortality of rodents on board, the cause of which is not known on arrival.

(b) An infected or suspected vessel or an infected aircraft shall be detained in quarantine as may be necessary for the effective accomplishment of the applicable sanitary measures prescribed in this part.

(c) On arrival of a vessel which has rodent plague on board the medical officer in charge shall require the deratting of the vessel. The following provisions shall apply to such deratting:

(1) The deratting shall be carried out as soon as the holds have been emptied;

(2) One or more preliminary derattings of a vessel with the cargo in situ, or during its unloading, may be carried out to prevent the escape of infected rodents;

(3) If the complete destruction of rodents cannot be secured because only part of the cargo is due to be unload-

ed, a vessel shall not be prevented from unloading that part, but the medical officer in charge may apply any measures which he considers necessary to prevent the escape of infected rodents.

(d) If a rodent dead of plague is found on board an aircraft, it shall be deratted.

§ 71.85 Plague. Vessels and aircraft: persons; things.

(a) Persons ill from plague shall be removed and isolated until no longer infectious.

(b) On arrival of an infected or suspected vessel or infected aircraft the medical officer in charge may:

(1) Require any suspect on board to be disinsected and may place him under surveillance, the period of surveillance being reckoned from the date of arrival of the vessel or aircraft;

(2) Require the disinsecting and, if necessary, disinfection of the baggage of any infected person or suspect and of any other article such as used bedding or linen, and any part of the vessel or aircraft, which the medical officer in charge considers to be contaminated.

(c) On the arrival of a healthy vessel or aircraft which has come from a plague infected local area the medical officer in charge may:

(1) Place under surveillance any suspect who disembarks, the period of surveillance being reckoned from the date of departure of the vessel or aircraft from the infected area;

(2) Require the deratting of the vessel in exceptional circumstances. In such case, the master shall be informed in writing of the reasons for the action.

(d) In exceptional circumstances of an epidemiological nature, when the presence of rodents is suspected on board, an aircraft may be deratted.

§ 71.86 Smallpox: Persons, general.

(a) All arriving persons shall be subject to vaccination against smallpox unless they present evidence satisfactory to the medical officer in charge of successful vaccination, or of a revaccination, within 3 years prior to arrival or of a previous attack of smallpox.

(b) Any person subject to vaccination under this section shall be offered vaccination; if he is not vaccinated, he may be placed under surveillance, the period of surveillance being reckoned from the date of his departure from the last territory visited prior to his arrival.

(c) Any person subject to vaccination under this section who has visited a smallpox infected local area within 14 days prior to arrival may be required to be vaccinated, or may be placed under surveillance, or may be vaccinated and then placed under surveillance; if he refuses vaccination, he may be isolated. The period of surveillance or isolation shall be reckoned from the date of departure from the infected local area.

§ 71.87 Smallpox: Infected vessels and aircraft; persons.

(a) For the purpose of applying sanitary and quarantine measures against the spread of smallpox, an infected vessel or aircraft means a vessel or aircraft which on arrival has a case of smallpox aboard or has had a case of smallpox on board during the voyage.

(b) On arrival of an infected vessel or aircraft the medical officer in charge shall detain the vessel or aircraft in quarantine as may be necessary for the effective accomplishment of the following measures:

(1) Persons ill from smallpox shall be removed and isolated until no longer infectious.

(2) Vaccination shall be offered to any person on board who the medical officer in charge considers is not sufficiently protected against smallpox.

(3) The medical officer in charge, taking into consideration the danger of infection, may place under surveillance or in isolation any person disembarking. The period of surveillance or isolation shall be reckoned from the last exposure to infection.

(4) The baggage of any infected person shall be disinfected.

(5) Any other baggage or article, or any part of the ship or aircraft, which the medical officer in charge considers to be contaminated shall be disinfected.

§ 71.88 Smallpox: Persons; suspects.

The medical officer in charge may apply the provisions of paragraph (b) of § 71.87 to any suspect who disembarks from a vessel or aircraft which is not an infected vessel or aircraft.

§ 71.89 Typhus and relapsing fever: Vessels and aircraft; persons; things.

(a) A vessel or aircraft on which a case of typhus or relapsing fever has occurred during the voyage shall be detained in quarantine as may be necessary for the effective accomplishment of the following measures:

(1) Removal and isolation of any infected person on board until he is no longer infectious.

(2) Disinsecting of any suspect on board.

(3) Disinsecting and, if necessary, disinfection of the accommodations occupied by any infected person or suspect, his clothing, baggage, and any other article which the quarantine officer considers is likely to spread typhus or relapsing fever.

(b) The medical officer in charge may:

(1) Require the disinsecting of any person who has left an infected local area within 14 days prior to arrival, in the case of typhus, and within 8 days prior to arrival, in the case of relapsing fever, and the disinsecting and, if necessary, disinfection of his clothing, baggage, and any other article which the quarantine officer considers is likely to spread typhus or relapsing fever.

(2) Place any person so disinsected under surveillance for a period of not more than 14 days in the case of typhus and not more than 8 days in the case of relapsing fever, such period of surveillance being reckoned from the date of the disinsecting.

§ 71.90 Yellow fever: Vessels and aircraft; classification.

For the purpose of applying sanitary and quarantine measures against the spread of yellow fever:

(a) An infected vessel means a vessel which has on board on arrival or which during its voyage had on board a case of yellow fever.

(b) An infected aircraft means an aircraft which has on board on arrival a case of yellow fever.

(c) A suspected vessel means a vessel which has left a yellow fever infected local area within 6 days prior to arrival or which arriving within 30 days after leaving such area has Aedes aegypti on board.

(d) A suspected aircraft means an aircrat which has left an airport situated in a yellow fever infected local area bound for a yellow fever receptive area in the United States if on arrival the quarantine officer is not satisfied that it was adequately disinsected before departure from such area or in flight and finds live mosquitoes on board.

(For disinsecting requirements for aircraft and vessels see §§ 71.102 and 71.103.)

[22 FR 6461, Aug. 13, 1957]

§ 71.91 Yellow fever: Vessels and aircraft; persons.

(a) On arrival of an infected vessel or aircraft the quarantine officer shall remove and isolate all persons ill with yellow fever until no longer infectious.

(b) In a yellow fever receptive area the medical officer in charge may place in isolation or under surveillance any person arriving from an infected area or disembarking from an infected or suspected vessel or aircraft who does not produce a valid certificate of vaccination against yellow fever, until his certificate becomes valid or for not more than 6 days from the date of last possible exposure, whichever is earlier.

(c) At a port outside the yellow fever receptive area the medical officer in charge, taking into consideration the risk of introduction of yellow fever, may place in isolation or under surveillance any person arriving from an infected area or disembarking from an infected or suspected vessel or aircraft who does not produce a valid certificate of vaccination against yellow fever if such person is bound for a yellow fever receptive area and expects to arrive in such area before his certificate becomes valid or within 6 days from the date of last possible exposure, whichever is earlier. The period of surveillance or isolation authorized by this paragraph shall not extend beyond the earlier of the dates specified herein.

Subpart G—Sanitary Inspection: Control of Rodents, Insects, and Other Vermin; Disinfection

SOURCE: 22 FR 6461, Aug. 13, 1957; 22 FR 6963, Aug. 29, 1957, unless otherwise noted.

§ 71.101 General provisions.

Vessels or aircraft arriving at a port under the control of the United States from a foreign port shall be subject to sanitary inspection to ascertain whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary condition requiring measures for the prevention of the introduction, transmission, or spread of communicable disease. (For sanitary measures with respect to border traffic see § 71.140.)

§ 71.102 Disinsection of aircraft.

(a) The Director, Center for Disease Control, may require disinsection of an aircraft if it has left a foreign area that is infected with insect-borne communicable disease and is suspected of harboring insects of public health importance.

(b) Disinsection shall be the responsibility of the pilot in command, and subject to monitoring by the Public Health Service Officer in charge.

(c) Disinsection of the entire aircraft shall be accomplished immediately after landing and blocking.

(d) The cargo compartment shall be disinsected before the mail, baggage, and other cargo are discharged.

(e) The rest of the aircraft shall be disinsected after passengers and crew deplane.

(f) The insecticides used shall be either (1) Insecticide Aerosol Resmethrin—2% or (2) Insecticide Aerosol d-Phenothrin—2%. The formulas for these insecticides are set forth below. Personnel shall disinsect aircraft in accordance with the instructions contained in the labeling accompanying the particular insecticide.

FORMULA FOR INSECTICIDE AEROSOL; RESMETHRIN—2%

Component	By weight (percent)
Active Ingredients: [1](5-Benzyl-3-furyl) methyl 2, 2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate	2.00
Inert Ingredients	98.00
	100.00

[1] Cis/trans ratio: max. 11% (±) cis. and min. 89% (±) trans.

FORMULA FOR INSECTICIDE AEROSOL; D-PHENOTHRIN—2%

Component	By weight (percent)	By weight (percent)
Active Ingredient:		
3-phenoxybenzyl d-cis and trans[1] 2, 2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate	2.00	1.92
Other Isomers		0.08
Inert Ingredients	98.00	98.00
	100.00	100.00

[1] Cis/trans isomer ratio: max. 25% (±) cis and min. 75% (±) trans.

[44 FR 58912, Oct. 12, 1979]

§ 71.103 Disinsecting and disinfesting vessels.

(a) *Disinsecting (yellow fever).* (1) The following vessels shall be disinsected:

(i) An infected vessel as defined in § 71.90.

(ii) A vessel arriving from a yellow fever infected local area, if it has not been adequately disinsected before arrival.

(iii) A vessel that has left a port where Aedes aegypti exists and arrives at a port under the control of the United States that has been freed of Aedes aegypti, if it has not been adequately disinsected before arrival.

(2) In a yellow fever receptive area infected vessels shall be moored at least 400 meters from the land until disinsecting required by this paragraph is completed. Other vessels that are required to be disinsected under this paragraph shall be so moored when deemed necessary by the medi-

cal officer in charge to prevent the introduction of vectors of yellow fever.

(3) The medical officer in charge shall accept prearrival disinsecting as adequate if after inspection he determines that such disinsecting has been effective, and the insecticide and disinsecting methods meet the requirements specified for aircraft in § 71.102(b), except that the ventilation system shall be stopped and all openings to the exterior kept closed for a period of at least 15 minutes after the insecticide is released or sprayed.

(b) *Disinfesting (general).* A vessel may be disinfested on arrival if the medical officer in charge considers disinfestation necessary to prevent the spread of infection or for the destruction of insects and other vermin capable of transmitting communicable disease.

§ 71.104 Disinsecting and disinfection of persons and things; vessels and aircraft.

The person, effects, and baggage of any vermin infested person arriving aboard a vessel or aircraft shall be disinsected and, if necessary in the judgment of the medical officer in charge, disinfected.

§ 71.105 Deratting Certificates: Deratting Exemption Certificates; vessels only.

If a valid Deratting Certificate or Deratting Exemption Certificate is not produced with respect to any arriving vessel the medical officer in charge shall:

(a) If he is satisfied that the vessel is free of rodents or is kept in such a condition that the number of rodents on board is negligible, issue a Deratting Exemption Certificate.

(b) If he is satisfied that a Deratting Exemption Certificate should not be issued with respect to such vessel, require the deratting of the vessel. When deratting has been completed to the satisfaction of the medical officer in charge, he shall issue a Deratting Certificate.

§ 71.106 Deratting: Aircraft only.

An aircraft may be deratted in exceptional circumstances of an epidemiological nature when the medical officer in charge suspects the presence of rodents on board.

§ 71.107 Issuance of Deratting Certificates and Deratting Exemption Certificates: Approved and designated stations.

In accordance with Article 17 of the International Sanitary Regulations, all quarantine stations of the Public Health Service are approved and designated for the issuance of Deratting Certificates and Deratting Exemption Certificates.

§ 71.108 Vessels and aircraft in intercoastal and interstate traffic.

Vessels and aircraft in traffic between ports under the control of the United States shall be subject to sanitary inspection as described in § 71.101, when arriving from a port infected or suspected of being infected with quarantinable disease or when illness on board indicates unsatisfactory sanitary conditions.

§ 71.109 Application of sanitary measures.

The sanitary measures prescribed by § 71.68 and Subpart F of this part shall be applicable after sanitary inspections made pursuant to this subpart.

Subpart H—Pratique: Vessels and Aircraft

§ 71.121 General requirement: Vessels only.

Vessels subject to quarantine inspection pursuant to Subpart D of this part shall not enter a port under the control of the United States to discharge cargo or land passengers unless a certificate of free or provisional pratique has been issued to the master.

§ 71.122 Free pratique: Vessels only.

A certificate of free pratique shall signify that the vessel and its master may enter, discharge cargo, and land passengers.

§ 71.123 Provisional pratique and remand: Vessels only.

(a) A certificate of provisional pratique shall signify that the vessel may enter, but that additional measures as specified in such certificate must be taken in connection with the discharge of cargo, or the landing of passengers, or the sanitary condition of the vessel. A certificate of free pratique shall be issued after such additional measures have been completed.

(b) The medical officer in charge may remand the vessel to the next port for such additional measures as may be necessary. Vessels arriving at quarantine stations at succeeding ports of call under provisional pratique may, in the discretion of the medical officer in charge at such stations, be directed to proceed under provisional pratique to the next succeeding port for completion of quarantine measures.

(c) Failure to comply with additional measures specified in a certificate of provisional pratique shall constitute a violation of the regulations in this part, and the vessel shall become subject to all measures applicable to vessels first arriving at a port under the control of the United States from a foreign port.

§ 71.124 Radio pratique: Vessels only.

The medical officer in charge may grant pratique by radio to a vessel upon the basis of information regarding the vessel, its cargo and persons aboard, received prior to arrival of the vessel, when in his judgment, and in accordance with instructions by the Surgeon General, the entry of the vessel will not result in the introduction, transmission or spread of communicable diseases.

§ 71.125 Presentation of pratique: Vessels only.

Vessels which have undergone quarantine inspection shall present to the Collector of Customs at the port of entry the certificate of pratique, or evidence of radio pratique, issued pursuant to the provisions of this subpart.

§ 71.126 Pratique and remand: Aircraft only.

When all necessary quarantine and sanitary measures have been applied to the aircraft and persons and things on board, pursuant to the regulations of this part, the quarantine officer shall issue a certificate of free pratique, which may be stamped on a copy or copies of the general declaration, including the traveling general declaration, for presentation to the customs officer in charge. Pending compliance with quarantine requirements the qurantine officer may issue a certificate of provisional pratique for the aircraft, stating the measures to be carried out. When quarantine measures cannot be completed at the place of first landing, the medical officer in charge may remand the aircraft under provisional pratique to the next airport for such additional measures as may be necessary. Aircraft arriving under provisional pratique at succeeding airports may, when quarantine measures cannot be completed there, be directed to proceed under provisional pratique to the next succeeding airport for completion of quarantine measures.

§ 71.127 Notification of remands: Vessels and aircraft.

The quarantine officer remanding a vessel or aircraft to another port in accordance with this subpart shall give advance notification to the medical officer in charge and customs officer at the port to which the vessel or aircraft is remanded. The notification should be timed to arrive ahead of the vessel or aircraft, and should be made by telephone in the case of aircraft. The notification shall give complete information regarding measures carried out at the port effecting the remand and measures required at the port to which the vessel or aircraft is remanded.

§ 71.128 Vessels and aircraft not submitting to prescribed measures.

When it is desired not to comply with the requirements for a certificate of free or provisional pratique, a vessel or aircraft shall be allowed to depart forthwith, but shall not call at any other place in the United States in connection with the current voyage or flight. The vessel or aircraft shall, however, be permitted to take on fuel, water, and stores in quarantine subject to measures prescribed by the quarantine officer pursuant to the regulations in this part.

Subpart I—Border Quarantine

§ 71.136 Applicability.

The special provisions of this subpart apply to the entry of persons and things (including conveyances) into the United States by land transit. The Surgeon General may exempt certain areas from these provisions. (See the provisions of Subpart J, regarding the importation of certain things which are applicable at all ports of entry, including border ports.)

§ 71.137 Ports of entry: Inspection.

A person shall not enter except at established ports of entry, and after such inspection by a quarantine officer as the office deems necessary to carry out the provisions of the regulations in this part.

§ 71.138 Infected persons: General rule.

All infected persons shall be removed and isolated until no longer infectious.

§ 71.139 Persons, conveyances, things: Specific diseases.

For the purpose of preventing the introduction, transmission, or spread of quarantinable disease, the following measures are prescribed:

(a) *Cholera.* (1) Any person who, within 5 days prior to arrival, has departed from a local area infected with cholera may be placed under surveillance if he has a valid certificate of vaccination against cholera or may be placed in isolation if he does not have such a certificate. The period of isolation or surveillance shall be reckoned from the date of departure of the person from the infected area.

(2) If a case of cholera is discovered aboard an arriving train or road vehicle the medical officer in charge may place any suspect under surveillance, the period of surveillance being reckoned from the date of arrival. He may require the disinfection of personal effects and baggage of the infected person or any suspect, and of any other article, such as used bedding or linen, and any part of the train or road vehicle considered to be contaminated.

(3) On arrival of a train or a road vehicle coming from a cholera infected local area or on which a case of cholera has been discovered, the medical officer in charge may prohibit the unloading of, or may remove, all fish, shellfish, fruit or vegetables to be consumed uncooked, or beverages, unless such food or beverages are in sealed containers and the medical officer in charge has no reason to believe that they are contaminated. If any such food or beverage is so removed it shall be safely disposed of.

(b) *Yellow fever.* On arrival in a yellow fever receptive area, any person coming from a yellow fever infected local area who is unable to produce a valid certificate of vaccination against yellow fever may be isolated or placed under surveillance until his certificate becomes valid or for not more than 6 days from the date of last possible exposure, whichever is earlier. Any such person arriving outside a yellow fever receptive area and bound for such an area shall be subject to the applicable measures provided in § 71.91(c).

(c) *Smallpox.* (1) All arriving persons shall be subject to vaccination, surveillance and isolation as provided in § 71.86.

(2) If a case of smallpox is discovered on an arriving train or road vehicle, all persons and articles aboard such train or road vehicle shall be subject to the measures provided for in paragraphs (2), (3), (4) and (5) of § 71.87(b) and any part of the train or road vehicle considered by the medical officer in charge to be contaminated shall be disinfected. Any period of isolation or surveillance shall be reckoned from the date of arrival.

(3) The medical officer in charge may apply the measures provided for in paragraphs (2), (3), (4) and (5) of § 71.87(b) to any suspect who arrives in the United States by any means of land transit.

(d) *Plague.* (1) If a case of human plague is discovered on an arriving train or road vehicle, all persons and articles aboard such train or road vehicle shall be subject to the measures provided for in paragraphs (1) and (2) of § 71.85(b) and any part of the train or road vehicle considered by the medical officer in charge to be contaminated shall be disinsected and if necessary disinfected.

(2) Any arriving suspect, his baggage and effects, may be disinsected and, if necessary, disinfected, and he may be placed under surveillance, the period of surveillance being reckoned from the date of his last possible exposure.

(e) *Typhus and relapsing fever.* (1) Any person arriving from an area infected with typhus or relapsing fever shall be subject to the measures provided for in § 71.89(b).

(2) If a case of typhus or relapsing fever is discovered on an arriving train or road vehicle, all persons, their accommodations and articles on board shall be subject to the measures provided for in paragraphs (2) and (3) of § 71.89(a).

§ 71.140 Disinsecting and disinfestation of persons, things, and conveyances.

(a) All vermin infested persons, their wearing apparel, baggage and personal effects shall be disinsected when deemed necessary by the medical officer in charge.

(b) Trains, road vehicles, merchandise, and baggage or other effects may be disinsected or disinfested on arrival if the medical officer in charge considers disinsecting or disinfestation necessary to prevent the spread of infection or for the destruction of insects and vermin capable of transmitting communicable disease.

§ 71.141 Communicable diseases other than quarantinable diseases.

The provisions of § 71.68 shall be applicable to persons and things (including conveyances) arriving in the United States by land transit.

Subpart J—Importation of Certain Things

§ 71.151 Lather brushes.

(a) *Conditions for entry.* Shipments of lather brushes made from animal hair or bristles intended for sale, resale or other distribution shall be denied entry into any port or place under the control of the United States unless such shipments conform with the requirements of this section.

(b) *Identifying mark.* The handles of such brushes shall be permanently marked with the name of the country where the brushes were manufactured and the name of the manufacturer or an identifying symbol, word, device, or other mark which is distinctly associated with the manufacturer.

(c) *Certification.* Each shipment of lather brushes shall be accompanied by a certification, to be submitted to the District Director of Customs, that the brushes have been treated and stored during and subsequent to manufacture in accordance with procedures and methods which prevent contamination or recontamination with viable vegetative forms and spores of *Bacillus anthracis.* The certification shall be in English; it shall identify the manufacturer and bear or describe in detail any identifying symbol, word, device, or other mark placed on the handle of the brush in accordance with paragraph (b) of this section; and it shall be signed by the manufacturer or an authorized representative.

(d) *Special requirements.* The Director, Center for Disease Control, may, as he considers necessary to prevent the introduction, transmission, or spread of communicable disease, deny entry of any shipment of lather brushes pending the laboratory examination of samples of the shipment to determine the presence or absence of viable vegetative forms and spores of *Bacillus anthracis.* If such examination indicates that the shipment is free from viable vegetative forms and spores of *Bacillus anthracis,* the Quarantine Officer in Charge shall furnish the District Director of Customs a certificate to that effect. If such examination indicates that the shipment is not free from viable vegetative forms and spores of *Bacillus anthracis,* the Quarantine Officer in Charge shall notify the District Director of Customs that the shipment shall be denied entry.

(e) *Disposal of shipments denied entry.* Shipments of brushes which are denied entry may be returned to the country of origin, within a reasonable period of time, as determined by the Quarantine Officer in Charge, at the expense of the manufacturer or shipper, or be destroyed.

[43 FR 53039, Nov. 15, 1978]

§ 71.154 Importation requirements for dogs and cats.

(a) *Definitions.* As used in this section and § 71.155, which deals with disposition of excluded dogs and cats, the term:

"Cat" means a domestic cat.

"Confinement" means restriction of a dog or cat to a building or other enclosure at the port of entry, en route to destination, and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

"Director" means the Director, Center for Disease Control, Public Health Service, U.S. Department of Health and Human Services, or the person to whom the authority involved has been delegated.

"Dog" means a domestic dog.

"Owner" means owner or agent.

"United States" means the States, the District of Columbia, Puerto Rico, and the Virgin Islands.

"Valid rabies vaccination certificate" means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(i) Identifies a dog on the basis of breed, sex, age, color, markings, or other information.

(ii) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog.

(iii) Specifies a date of expiration which is after the date of arrival of the dog. If no date of expiration is specified, the date of vaccination may be no more than 12 months before the date of arrival.

(iv) Bears the signature of a licensed veterinarian.

(b) *General requirements for admission of dogs and cats.* Dogs and cats may not be brought into the United States except as provided in this section.

(1) *Inspection by quarantine officer.* Dogs and cats which arrive in the United States from a foreign area shall be subject to inspection by a quarantine officer at a port of entry. The quarantine officer shall admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1(b).

(2) *Examination by veterinarian and confinement of dogs and cats.* When a dog or cat does not appear to be in good health on arrival (that is, it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the officer in charge may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The officer in charge will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment required by the officer in charge. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the officer in charge will afford protection against introduction of any communicable disease.

The owner shall bear the expense of confinement. Release shall be subject to conditions specified by the officer in charge to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for exposed animals.* (i) The person responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine officer at the port of entry. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered. They shall be held in confinement pending any necessary examination (and treatment of any sick dog or cat) as determined to be necessary by the officer in charge.

(ii) Regardless of the provisions of paragraph (b)(1) of this section, when a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section relating to examination, tests, confinement, treatment, payment, and release shall apply to these dogs and cats.

(4) *Sanitation*. When the quarantine officer finds that the cages or other containers of dogs or cats arriving in the United States are in an unsanitary or other condition that may constitute a communicable disease hazard:

(i) The dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected; and

(ii) The quarantine officer shall report the matter to the U.S. Customs Service Officer for investigation pursuant to U.S. Customs regulations (19 CFR 12.26(k)) regarding importation of animals under inhumane or unhealthful conditions.

(c) *Rabies vaccination requirements for dogs*. (1) The quarantine officer shall require submittal of a valid rabies vaccination certificate at the port of entry for admission of a dog into the United States unless the owner submits evidence satisfactory to the quarantine officer that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free;[1] or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country or countries determined by the Director to be rabies-free;[1] or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1), the quarantine officer may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but it must be kept in confinement until at least 30 days have elasped since the date of vaccination.

(ii) If the dog is less than 3 months of age, it may be admitted, but it must be kept in confinement until it is vaccinated against rabies at 3 months of age. Also, it must be kept in confinement for at least 30 days after the date of vaccination.

(iii) If the dog is 3 months of age or older, it may be admitted, but it must be kept in confinement until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at port of entry. Also, it must be kept in confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the quarantine officer shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the health department with the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements*. The owner shall submit certifications regarding prior residence, destination, confinement, and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats*. Dogs and cats coming from areas having a high rate or other special danger of rabies shall be subject to additional requirements or exclusion as may be determined by the Director to be necessary to protect the public health.

(f) *Requirements for dogs and cats in transit*. The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as provided in paragraph (b)(3) of this section if the quarantine officer determines that the conditions under which

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[1] A current list of rabies-free countries may be obtained from the Director, Quarantine Division, Bureau of Epidemiology, Center for Disease Control, Atlanta, Georgia 30333.

they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or vessel and retained in custody of the carrier under conditions preventing introduction of rabies.

(Sec. 215, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 361, 58 Stat. 703 (12 U.S.C. 264))

[45 FR 12253, Feb. 25, 1980]

§ 71.155 Dogs and cats; disposal of excluded animals.

A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exporation it shall be detained in Custom's custody at the port of arrival at the owner's expense.

[40 FR 33661, Aug. 11, 1975]

§ 71.156 Etiological agents and vectors.

(a) A person shall not import into any place under the control of the United States, nor distribute after importation, any etiological agent or insect, animal or plant vector of human disease or any exotic living insect, animal or plant capable of being a vector of human disease unless accompanied by a permit issued by the Surgeon General.

(b) An article or thing coming within the provisions of this section shall not be released from Customs' custody prior to the receipt by the Collector of Customs of a permit therefor issued by the Surgeon General.

§ 71.157 Dead bodies.

The remains of a person dead from a quarantinable disease shall not be brought into a port under the control of the United States unless it is (a) properly embalmed and placed in a hermetically sealed casket, or (b) cremated.

Subpart J-1—Importation of Psittacine Birds

SOURCE: 32 FR 14058, Oct. 10, 1967, unless otherwise noted.

§ 71.161 Definitions.

As used in this subpart, the term:

(a) "Psittacine birds" includes birds commonly known as parrots, Amazons, African grays, cockatoos, macaws, parrotlets, beebees, parakeets, lovebirds, lories, lorikeets, and all other birds of the order Psittaciformes.

(b) "United States" means the United States, its territories, and possessions (other than the Canal Zone).

§ 71.162 Requests for information.

All requests for instructions, application forms, and other information relating to the regulations in this part should be addressed to the Chief, Foreign Quarantine Program, National Communicable Disease Center, U.S. Public Health Service, Atlanta, Ga. 30333, or to Public Health Service quarantine stations at U.S. ports of entry.

§ 71.163 Psittacine bird treatment centers.

(a) *Approval of treatment centers*—(1) *Minimum standards for approval.* To be eligible for approval, psittacine bird treatment centers shall meet the following minimum standards and such other requirements as shall be determined by the Surgeon General as necessary for the proper care and treatment of psittacine birds.

(i) They will be located outside of the United States.

(ii) They will be so constructed as to provide adequate sanitation.

(iii) They will be under the direction and supervision of a director approved by the Surgeon General as qualified by experience, education, and training to supervise and direct the operations of the center.

(iv) They will provide access to the treatment center and to books and records thereof, to authorized representatives of the Surgeon General for inspection purposes.

(v) They will, upon request of the Surgeon General, provide samples of psittacine birds and specimens of psittacine bird blood, food, feces, medication, and related material which the Surgeon General deems necessary to ascertain the compliance of the center with procedures and medication approved by the Surgeon General for psittacine bird treatment.

(vi) They will maintain complete records of all birds received, treated, and shipped including date of each shipment, and name and address of consignee.

(2) *Application for approval.* Application for approval of a treatment center shall be addressed to: Chief, Foreign Quarantine Program, National Communicable Disease Center, U.S. Public Health Service, Atlanta, Ga. 30333. The application shall be made on a form prescribed by the Surgeon General and shall provide the following information and any other information which the Surgeon General may deem necessary in determining that satisfactory disease prevention measures will be provided in the care, treatment, shipment, and handling of psittacine birds.

(i) The name and address of the treatment center.

(ii) A detailed description of the treatment center including:

(*a*) A plat showing location of the treatment center building(s) with respect to other adjacent buildings and structures;

(*b*) Floor plans of the treatment center building(s); and

(*c*) A description of the type of building construction.

(iii) A statement of measures that will be used to maintain good sanitation and protect the health of the birds.

(iv) A statement of the method to be used for assaying the medication used in the treatment of the birds, and the name and address of the laboratory that will make the assays.

(v) Evidence satisfactory to the Surgeon General that the treatment center director meets the requisites of paragraph (a)(1)(iii) of this section.

(3) *Issuance of certificate of approval.* If the Surgeon General finds that the treatment center meets the requisites of approval as established by paragraphs (a) (1) and (2) of this section, he will issue a certificate of approval which will be valid until suspended or revoked.

(b) *Suspension of certificate of approval, and opportunity for hearing.* Whenever the Surgeon General has reasonable ground to believe that a treatment center is not conforming to the requirements of this subpart, he may, upon notice to the treatment center, suspend the certificate of approval, and provide reasonable opportunity for a hearing thereon. The hearing will be within the United States at a place designated by the Surgeon General.

(c) *Revocation of certificate of approval.* The Surgeon General shall revoke a certificate of approval whenever a treatment center whose certificate of approval has been suspended, fails to avail itself of the hearing opportunity; or when after such hearing, the Surgeon General determines that any of the reasons for suspension remain uncorrected and warrant revocation.

(d) *Reinstatement of certificate of approval.* A certificate of approval which has been suspended may be reinstated upon a showing of compliance with required standards and upon such inspection, examination and assurance of continued compliance as may be considered necessary by the Surgeon General.

§ 71.164 Entry restrictions.

(a) *Health of birds*—(1) *Disease-free appearance.* Except for birds brought in under the special provisions of paragraph (a)(3) of this section, and of paragraph (c) of this section, psittacine birds shall be permitted entry into the United States only if all birds in the shipment appear to the quarantine officer at the port of entry to be free from evidence of communicable disease.

(2) *Specimens for study by Public Health Service.* Upon arrival at a U.S. port of entry, of a shipment of psittacine birds from an approved psittacine bird treatment center, the quarantine officer may take specimens of psittacine bird blood, feces, medication, and related material from such shipment, for laboratory study. If the owner or his representative refuses permission for the taking of such specimens, the shipment shall be denied entry.

(3) *Admission of birds not appearing to be disease-free and of exposed birds.* When a bird, upon arrival at a U.S.

port of entry, shows symptoms suggestive of communicable disease (but other entry requirements are met), the medical officer in charge may authorize its admission and admission of healthy appearing birds in the shipment if he is satisfied that adequate protection against introduction of communicable disease will be provided by measures arranged and paid for by the owner. Such measures shall include immediate isolation of the birds and immediate care by a specific licensed veterinarian who shall provide necessary treatment with approved medication and report the birds' condition to the medical officer in charge before the birds are released from isolation.

(b) *Entry document for birds from treatment centers.* Each shipment of psittacine birds from an approved treatment center shall be accompanied by an entry document prescribed by the Surgeon General. This document shall show the treatment center certificate of approval number, shall identify the birds by quantity and kind, shall show the name and address of the consignee, shall be subscribed and sworn to by the treatment center director, before a U.S. Consular or Embassy official in the country where the treatment center is located; and shall contain a certification by said director as to the following points:

(1) *Certification of treatment at treatment center.* That for a minimum of 45 consecutive days immediately before shipment to the United States the birds have been confined in said treatment center and treated with chlortetracycline, or other approved medication, prepared and administered in accordance with procedures approved by the Surgeon General for psittacosis control.

(2) *Certification of treatment and segregation of birds during shipment to the United States.* That arrangements have been made whereby such medication will be continued during shipment of psittacine birds to the United States, that during such shipment said birds will be confined in different cages from any other birds, and that said cages and any other containers therefor will be so constructed as to permit easy observation of the birds.

(c) *Birds imported for medical research.* Psittacine birds intended for use in medical research may be permitted entry into the United States without prior confinement and treatment if the following conditions are met.

(1) *Permit.* They are accompanied by a permit issued by the Surgeon General. Application for the permit shall be submitted by the person seeking to import the birds for medical research purposes, and shall contain such information and assurances as the Surgeon General may require concerning use of the birds in the proposed research.

(2) *Scientific use.* The scientific basis for the use of untreated birds is established to the satisfaction of the Surgeon General.

(3) *Protection against disease.* The birds are imported under conditions prescribed by the Surgeon General to minimize the risk of introduction of communicable disease into the United States.

(4) *Disease-free appearance.* They appear to the quarantine officer at the port of entry to be free from evidence of communicable disease, unless otherwise specified in the permit, or admission is authorized pursuant to paragraph (a)(3) of this section.

(d) *Certain birds imported by a zoological park.* Psittacine birds which, in the opinion of the Surgeon General, cannot be treated satisfactorily as specified in paragraph (b)(1) of this section at an approved treatment center outside the United States, may be imported by a zoological park without prior confinement and medication if the following conditions are met.

(1) *Permit.* They are accompanied by a special permit issued by the Surgeon General, pursuant to an application made therefor.

(2) *Restriction on disposition of birds.* Assurance is given that the birds will not be sold or given, either directly or indirectly, to any private individual or dealer in birds.

(3) *Disease-free appearance.* They appear to the quarantine officer at the port of entry to be free from evidence of communicable disease, unless ad-

mission is authorized pursuant to paragraph (a)(3) of this section.

(4) *Treatment facilities and staff.* The zoological park has a staff veterinarian and facilities for isolating psittacine birds, and has been approved by the Surgeon General for purposes of the regulations in this part.

(5) *Isolation and treatment.* On arrival at the zoological park the birds will be isolated for at least 45 days, and throughout that period will be treated with approved medication under conditions satisfactory to the Surgeon General.

(e) *Birds imported as pets.* Psittacine birds intended as pets may be imported by the persons who intend to keep them as pets, without prior confinement and treatment, if the following conditions are met.

(1) *Disease-free appearance.* The birds appear to the quarantine officer at the port of entry to be free from evidence of communicable disease, unless admission is authorized pursuant to paragraph (a)(3) of this section.

(2) *Certificate.* The owner submits a written statement certifying the following points.

(i) That not more than a total of two (2) birds are imported under this paragraph in any 12-month period by members of a family comprising a single household.

(ii) That the birds are not intended for sale or trade in the United States.

(iii) That the requirements of (e)(2)(iii) (*a*) or (*b*) and of (*c*) of this section, will be met.

(*a*) If the birds have been in the owner's possession and personal custody for at least 90 days immediately before arrival, except for any period occasioned by arrival of the owner and birds on separate conveyances, the owner shall submit a written certification that upon admission, the birds will be treated for 45 days with chlortetracycline or other approved medication. Medication may be administered on the premises of the owner of the birds, but must be under the supervision of a licensed veterinarian, and at the owner's expense. If the owner has not made the necessary arrangements with a licensed veterinarian before arrival of the birds, they shall be excluded unless he arranges for such supervision promptly upon their arrival at the port of entry. Pending such arrangements, the owner shall have the birds held in such a manner that the quarantine officer is satisfied that they do not present a serious health hazard.

(*b*) If the birds have been in the owner's possession and personal custody immediately before arrival, but for less than 90 days, the owner shall certify in writing that upon admission, the birds will be confined and treated with chlortetracycline or other approved medication for 45 days, in detention facilities on the premises of and under immediate care of a licensed veterinarian. Detention and medication will be accomplished at the owner's expense. Such veterinarian's detention facilities may be located either at the port of arrival or elsewhere in the United States. If the owner has not made the necessary arrangements with a veterinarian before arrival of the birds, they shall be excluded unless he promptly makes such arrangements with a veterinarian on whose premises the required detention and medication will be accomplished. Pending the making of such arrangements, the owner shall provide for having the birds held in such a manner that the quarantine officer is satisfied that they do not present a significant health hazard.

(*c*) The owner or the veterinarian shall report promptly to the quarantine officer at the port of entry any sickness or death of the birds during the required period of medication and follow the quarantine officer's instructions concerning measures to prevent the spread of infection.

(f) *Birds being returned to the United States.* When psittacine birds have been taken out of the United States and the requirements of paragraph (e) of this section are not fully complied with upon their return, they may be admitted provided the following conditions are met.

(1) *Disease-free appearance.* They appear to the quarantine officer at the port of entry to be free from evidence of communicable disease, unless admission is authorized pursuant to paragraph (a)(3) of this section.

(2) *Permit.* They are accompanied by a permit for return issued by the Surgeon General. Application for such permit may be denied unless the owner of the birds applies for the permit before their departure from the United States and the application includes a statement as to the itinerary, the number and description of the birds, and such other information as the Surgeon General may require.

(3) *Required information and certification.* At the port of entry the owner furnishes any information that may be required by the Surgeon General, and submits a written statement certifying the following.

(i) That he has complied with the terms of the permit.

(ii) That upon admission the birds will be treated for 45 days with chlortetracycline or other approved medication. The medication may be administered on the premises of the owner of the birds, but must be under the supervision of a licensed veterinarian, and at the owner's expense.

(iii) That the owner has arranged with a licensed veterinarian for such supervision. If the owner has not made the necessary arrangements before arrival of the birds, they shall be excluded unless he arranges for such supervision promptly upon their arrival at the port of entry. Pending the making of such arrangements, the owner shall provide for having the birds held in such a manner that the quarantine officer is satisfied that they do not present a significant health hazard.

(iv) That the owner or the veterinarian will report promptly to the quarantine officer at the port of entry any sickness or death of the birds during the required period of medication, and follow the quarantine officer's instructions concerning measures to prevent the spread of infection.

(g) *Permits. Terms and cancellation.* Any permit issued under paragraph (c), (d), or (f) of this section may contain such conditions and safeguards as the Surgeon General may deem advisable. The permit shall be subject to cancellation if procured or used in a manner inconsistent with this section.

§ 71.165 Disposal of excluded birds.

(a) *Birds with healthy appearance.* Healthy appearing psittacine birds which are excluded from admission under these regulations shall, at the owner's option be exported or destroyed, or given to a research facility or zoological park under arrangements approved by the quarantine officer for preventing the spread of infection. Exportation shall be permitted only if the owner exports the birds within a reasonable time as determined by the medical officer in charge. Pending disposal, the birds shall be detained at the port of entry at the owner's expense.

(b) *Birds with symptoms suggestive of psittacosis.* Psittacine birds which show symptoms suggestive of psittacosis on arrival shall be destroyed promptly unless admission is authorized pursuant to paragraph (a)(3) of § 71.164. Psittacine birds which develop symptoms suggestive of psittacosis while detained pending disposal shall be destroyed promptly unless the medical officer in charge is satisfied that measures arranged and paid for by the owner will provide adequate protection against introduction of communicable disease into the United States.

§ 71.166 Penalties.

Any person violating any provision of §§ 71.161 through 71.165 shall be subject to punishment by fine of not more than $1,000 or imprisonment for not more than 1 year, or both, as provided in section 368(a) of the Public Health Service Act (42 U.S.C. 271(a)).

Subpart J-2—Importation of Turtles, Tortoises, Terrapins

SOURCE: 37 FR 24672, Nov. 18, 1972, unless otherwise noted.

§ 71.171 Definitions.

As used in this subpart:

(a) "Turtles" includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order *Testudinata*, class *Reptilia* except marine species (Families *Dermochelidae* and *Cheloniidae*).

(b) "Director" means the Director, Center for Disease Control, Health Services and Mental Health Administration, Department of Health and Human Services, Atlanta, Ga. 30333.

§ 71.172 Importation: general prohibition.

Except as otherwise provided in this subpart, viable turtle eggs and live turtles with a carapace length of less than 4 inches may not be imported into the United States.

§ 71.173 Exceptions.

(a) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States: *Provided*, That such importation is limited to lots of less than seven (7) live turtles or less than seven (7) viable turtle eggs, or any combination of such turtles and turtle eggs totaling less than seven (7), for any entry.

(b) Lots of seven (7) or more viable turtle eggs or seven (7) or more live turtles with a carapace length of less than 4 inches, or any combination of such turtles and turtle eggs totaling seven (7) or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(c) The requirements in paragraphs (a) and (b) of this section shall not apply to the eggs of marine turtles excluded from this regulation under § 71.171(a).

§ 71.174 Application for permits.

Application for permits to import lots of seven (7) or more viable turtle eggs or seven (7) or more live turtles with a carapace length of less than 4 inches, or any combination of such turtles and turtle eggs totaling seven (7) or more, for the purposes set forth in § 71.173, shall be made by letter to the Director, and shall contain, identify, or describe the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities; the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with bacteria of the *Salmonella* and *Arizona* genera and such other information and assurances as the Director may deem necessary to protect the public health.

§ 71.175 Issuance of permits; criteria.

A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to avoid infection of members of the public with bacteria of the *Salmonella* and *Arizona* genera and on condition that the holder of the permit will provide such reports as may be required by the Director to protect the public health.

§ 71.176 Penalties.

Any person violating any provision of this subpart shall be subject to a fine of not more than $1,000 or imprisonment for not more than 1 year, or both, as provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

Subpart J-3—Importation of Nonhuman Primates

SOURCE: 40 FR 33662, Aug. 11, 1975, unless otherwise noted.

§ 71.181 Definitions.

As used in this subpart:

(a) "Nonhuman primates" means all nonhuman primates of the Order Primates, including, but not limited to, animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarin, lemurs, lorises, and tree shrews.

(b) "Group" means a population of nonhuman primates which are physically isolated from other nonhuman primates. All nonhuman primates housed in one room of a facility constitute a group if they are effectively separated by solid partitions from other nonhuman primates.

(c) "Importer" means any person who, or corporation, partnership, or other organization which, receives live nonhuman primates within a period of 31 days beginning with the day of importation, whether or not such primates were held for part of such period at another location. As used in this Subpart J-3, the term "importer" includes the original importer and any other person or organization receiving such primates within a period of 31 days beginning with the day of importation.

(d) "Director" means the Director, Center for Disease Control, Public Health Service, Department of Health and Human Services, Atlanta, Georgia 30333.

§ 71.182 Importation; general prohibition.

Except as otherwise provided in this subpart, no person may import live non-human primates into the United States unless such person is registered as an importer in accordance with applicable provisions of this subpart.

§ 71.183 Importation and distribution; permissible purposes.

Live nonhuman primates may be imported into the United States and sold, resold, or otherwise distributed only for bona fide scientific, educational, or exhibition purposes in accordance with applicable provisions of this subpart.

§ 71.184 Registration of importers.

(a) Importers shall register with the Director on forms available from, and in a manner prescribed by the Director.

(b) Registration shall be effective for a calendar year or for such part thereof as remains following the date on which receipt of the properly completed registration form is acknowledged by the Director.

(c) Registration may be renewed by filing the appropriate forms with the Director not less than 30 days nor more than 60 days prior to the expiration of the period for which registration was effective.

§ 71.185 Recordkeeping and reporting.

(a) Importers shall maintain records on forms available from, and in a manner prescribed by, the Director relating to number of primates imported, countries of origin, species, dates of importation, dates of shipment to other persons or organizations, disease incidence, and such other information as may be requested by the Director. Such records shall be available for inspection by the Director at any time.

(b) Importers who receive 500 or more nonhuman primates in a calendar year shall submit quarterly reports, and importers who receive fewer than 500 nonhuman primates shall submit annual reports, on forms available from, and in a manner prescribed by, the Director. The reports shall specify numbers of primates imported, countries of origin, species, dates of importation, dates of shipment to other persons or organizations, disease incidence, and such other information as may be requested by the Director. Importers required to make quarterly reports shall submit the reports on or before April 30 for the preceding period of January through March, July 31 for the preceding period of April through June, October 31 for the preceding period of July through September, and January 31 for the preceding period of October through December. The first quarterly report shall be filed for the quarter during which a total of 500 imported nonhuman primates is reached. The first quarterly report shall include the information specified above in this paragraph (b) on all nonhuman primates imported in the preceding quarter or quarters of the calendar year. Quarterly reports will be required thereafter for each quarter year period of such calendar year irrespective of the number of nonhuman primates imported or otherwise received during such period. Importers required to make annual reports shall submit the reports on or before January 31 for the preceding calendar year.

(c) Importers shall report to the Director by telephone (days, 404-633-3311; nights, weekends and holidays, 404-633-2176) within 24 hours the occurrence of (1) any illness in nonhuman primates that is suspected of being yellow fever, monkeypox, or Marburg disease, and (2) deaths resulting from any illness or illnesses within any consecutive 7-day period of 10 percent or more of a group consisting of 20 or more nonhuman primates.

(d) Importers shall report to the Director by telephone within 24 hours the occurrence of illness in any member of their staff suspected of being an infectious disease acquired from nonhuman primates.

§ 71.186 Disease control measures.

The Director is authorized upon receipt of evidence of exposure of nonhuman primates to a communicable disease that constitutes, or may constitute, a threat to public health to provide for or to require examination, treatment, detention, quarantine, seizure, or destruction of exposed animals. Such measures as may be prescribed shall be at the expense of the owner.

§ 71.187 Disposal of excluded animals.

A nonhuman primate excluded from the United States under the regulations in this Subpart J-3 shall, at the owner's option and expense, be exported, destroyed, or given to a scientific, educational, or exhibition facility under arrangements approved by the Director, for preventing the spread of infection. Exportation shall be permitted only if the owner exports the nonhuman primate within a reasonable time as determined by the Director. Pending exportation or other disposition pursuant to the provisions of this § 71.187, it shall be detained in Customs' Custody at the port of arrival at the owner's expense.

§ 71.188 Suspension and revocation.

(a) An importer's registration may be suspended or revoked by the Director if the Director finds, upon notice to the importer holding such registration, that the importer has failed to comply with any applicable provision of this subpart. The notice shall contain a statement of the grounds upon which the suspension or revocation is based, and, in the case of suspension, the action necessary to end such suspension.

(b) The importer may file an answer to the notice within 20 days after service thereof. Answers shall admit or deny specifically and in detail each allegation of the notice. Allegations of fact in the notice not denied or controverted by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after service of the notice may be deemed an admission of all matters of fact recited in the notice.

(c) Where an importer's registration has been suspended or revoked, the suspension may be terminated or the registration reinstated, as may be appropriate, upon such inspection, examination of records, conference with the importer, furnishing of such information, and assurance of compliance with the requirements of this subpart as may be deemed necessary by the Director.

(d) The importer shall be entitled to a hearing with respect to the suspension or revocation (not preceded by suspension) upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of such suspension or revocation. Failure to request a hearing shall be deemed a waiver of hearing and consent to submission of the case to the Director for decision on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of such information as is available.

(e) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this subpart, the Director shall render a final decision. A copy of such decision shall be served on the importer.

§ 71.189 Penalties.

Any person who violates any provision of this subpart shall be subject to a fine of not more than $1,000 or imprisonment for not more than one year or both, as provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

Subpart K—Special Provisions Relating to Aircraft

§ 71.501 Scope.

(a) The term "aircraft", as used in this subpart, means civil aircraft, that is, aircraft not Government-owned and used exclusively in the governmental service of the United States or a foreign country, and includes any Government-owned aircraft engaged in carrying persons or property for commercial purposes.

(b) The term "international airport", as used in this subpart and in Subpart L of this part, means any airport designated by the Secretary of the Treasury or the Commissioner of Customs as a port of entry for aircraft arriving in the United States from any place outside thereof and for the merchandise carried on such aircraft, by the Attorney General as a port of entry for aliens arriving on such aircraft, and by the Secretary of Health and Human Services as a place for quarantine inspection.

(c) The term "United States", as used in this subpart, means the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands.

[21 FR 9870, Dec. 12, 1956, as amended at 25 FR 2531, Mar. 25, 1960]

§ 71.502 Place of landing.

(a) Every aircraft on an international flight and subject to quarantine inspection under Subpart D of this part shall make its first landing in the United States at an international airport, unless permission to land elsewhere has been granted by the Commissioner of Customs or other authorized customs officer with concurrence of the Public Health Service: *Provided*, That in cases in which such permission is not required by customs regulations, application for permission shall be made to the Surgeon General, for aircraft operated by scheduled airlines, and to the medical officer in charge at or nearest the intended place of first landing, for all other aircraft.

(b) Unless such permission has been granted, the first landing shall also be made at an international airport when conditions at the place of departure cause an aircraft to be subject to quarantine inspection on a flight between ports under control of the United States.

§ 71.503 Advance notice of arrival.

(a) Notice of intended flight shall be furnished either by or at the request of the aircraft commander to the medical officer in charge at or nearest the intended place of first landing in the case of aircraft coming to a port under the control of the United States from any place outside the United States, and in the case of an aircraft flying between ports under the control of the United States when the aircraft is subject to quarantine inspection. Such notice may be forwarded through the collector or other customs officer in charge in cases in which the customs regulations also require advance notice of arrival. The notice shall be furnished direct to the medical officer in charge in cases in which advance notice of arrival is not required by customs regulations.

(b) The notice shall specify the type of aircraft, the registration marks on it, the name of the aircraft commander, the place of last departure, the international airport or other place at which landing has been authorized, the number of aliens and citizens on board, and the estimated time of arrival. The notice shall be sent in time to enable the inspecting officers to reach the airport prior to arrival of the aircraft.

(c) Such notice is not required for aircraft of a scheduled airline arriving in accordance with a regular schedule filed with the Collector of Customs for the district in which the place of first landing is situated or with the medical officer in charge or immigration officer in charge at the place of landing.

§ 71.504 Emergency or forced landing.

When an emergency or forced landing in the United States is made by an aircraft coming from any port not under the control of the United States, or by any aircraft subject to quarantine inspection under Subpart D of this part, the aircraft commander shall not allow any things on board to be removed from the landing place, or allow any person on board to depart from the landing place, without permission of a quarantine officer, unless such removal or departure is necessary for purposes of safety, communication with governmental authorities, or the preservation of life, health, or property. As soon as practicable the aircraft commander, a member of the crew in charge, or the owner of the aircraft shall communicate with the nearest quarantine officer and report in full the circumstances of the flight and of the emergency or forced landing. Mail carried as such may be removed from the aircraft upon landing, but if removed shall be delivered at once to a responsible officer or employee of the Postal Service.

§ 71.505 Special sanitary treatment.

Any aircraft arriving from any foreign port or place which the quarantine officer declares to be of such menace that it cannot be adequately or safely handled at the airport of first or intended landing shall be required to proceed with all passengers and persons employed on board and all mail, baggage, cargo, or other contents on board, as may be designated by such officer, to an airport indicated by such officer to have adequate facilities for such treatment as shall be prescribed by him.

§ 71.506 Applicability of regulations: Penalties.

(a) The regulations appearing in this part are applicable to aircraft and to passengers, merchandise, and baggage carried thereon, in the absence of express provision to the contrary.

(b) Any person violating any regulation in this part relating to aircraft or any provision of the regulations made applicable to aircraft by this section shall be subject to punishment by fine or imprisonment as provided for in section 368(a) of the Public Health Service Act (42 U.S.C. 271(a)). Any aircraft which violates any regulation in this part relating to aircraft or any provision of the regulations in this part made applicable to aircraft by this section shall be subject to forfeiture as provided for in section 368(b) of the Public Health Service Act (42 U.S.C. 271(b)). Such forfeiture may be remitted or mitigated by the Surgeon General with the approval of the Secretary of Health and Human Services.

Subpart L—Special Provisions Relating to Ports and Airports

§ 71.601 Applicability.

The special provisions of this subpart apply to ports and airports under the control of the United States receiving international traffic.

§ 71.602 Food and drinking water: Ports and airports.

(a) Every port and airport shall be provided with a supply of pure drinking water from a watering point approved by the Surgeon General in accordance with standards established in § 72.102 of this chapter.

(b) All food and water taken aboard a vessel or aircraft at any port or airport intended for consumption thereon shall be obtained from sources approved by the Surgeon General pursuant to Part 72 of this chapter.

§ 71.603 Disposal of waste matter: Airports and aircraft.

(a) Every airport shall be provided with an effective system for the removal and safe disposal of excrement, refuse, waste water, condemned food, and other matter dangerous to health.

(b) Aircraft inbound or outbound on an international flight shall not discharge over the United States, its territories, or possessions any excrement, garbage, waste or waste water. Arriving aircraft shall discharge such matter only at a servicing area of an airport equipped with a system for safe disposal of said matter.

§ 71.604 Designation of sanitary airports.

An airport may be designated by the Surgeon General as a sanitary airport after due investigation to establish:

(a) That a sufficient need exists for such designation;

(b) That the airport has at its disposal:

(1) An organized medical service with adequate staff, equipment, and premises;

(2) Facilities for the transport, isolation, and care of infected persons or suspects;

(3) Facilities for efficient disinfection and disinsecting, for the destruction of rodents, and for any other appropriate measure provided for by the regulations in this part;

(4) A bacteriological laboratory, or facilities for dispatching suspected material to such a laboratory;

(5) Facilities for vaccination against cholera, yellow fever, and smallpox.

§ 71.605 Yellow fever areas: Sanitary requirements: Ports and airports.

(a) Every port, and the area within the perimeter of every airport, shall be kept free from Aedes aegypti in its larval and adult stages.

(b) Any building within a direct transit area provided at any airport situated in a yellow fever receptive area shall be mosquito proof.

(c) Every person employed at an airport situated in a local area infected with yellow fever and every member of the crew of an aircraft using any such airport shall be in possession of a valid certificate of vaccination against yellow fever.

(d) Every sanitary airport situated in a yellow fever receptive area shall:

(1) Be provided with mosquito-proof dwellings and have at its disposal mosquito-proof sick quarters for passengers, crews and airport personnel; and

(2) Be freed from mosquitoes by systematically destroying them in their larval and adult stages within the perimeter of the airport, and within a protective area extending for a distance of four hundred meters around that perimeter.

[21 FR 9870, Dec. 12, 1956, as amended at 22 FR 6464, Aug. 13, 1957]

§ 71.606 Perimeter: Airports only.

As used in this subpart, the perimeter of an airport means a line enclosing the airport buildings and any land or water used or intended to be used for the parking of aircraft.

§ 71.607 Withdrawal of designation.

The designation of an airport as a sanitary airport may be withdrawn by the Surgeon General after reasonable notice to the airport whenever he finds that the airport fails to comply with any applicable sanitary requirement prescribed in this subpart or fails to meet the conditions prescribed in §§ 71.602 and 71.603.

§ 71.608 Cholera and plague: Persons unloading vessels or aircraft.

(a) *Cholera.* Persons who unload a cholera infected vessel or aircraft, and in the judgment of the medical officer in charge have been exposed to risk of infection, shall be placed under surveillance for a period not to exceed five days from the time they cease unloading.

(b) *Plague.* Persons who unload a vessel or aircraft may be disinsected and placed under surveillance or in isolation for a period not to exceed six days from the time they cease unloading, if the vessel or aircraft is infected or during the voyage has been infected with human or rodent plague, or if inspection of the vessel or aircraft has revealed rodent mortality of undetermined cause, and in the judgment of the medical officer in charge such persons have been exposed to risk of infection.

§ 71.609 Designation of international airports.

(a) International airports (see § 71.501(b)) will be designated after due investigation to establish the fact that a sufficient need exists in any particular district or area to justify such designation and to determine the airport best suited for such purpose.

(b) A specific airport will be designated in each case, rather than a general area or district which may include several airports.

(c) The designation as an international airport may be withdrawn if it is found that the volume of business clearing through the port does not justify maintenance of inspection equipment and personnel, if proper facilities are not provided and maintained by the airport, if the rules and regulations of the Federal Government are not complied with, or if it be found that some other location would be more advantageous.

(d) International airports shall be municipal airports, unless particular conditions which prevail warrant a departure from this requirement.

(e) Each international airport shall provide without cost to the Government suitable office and other space for the exclusive use of Federal officials connected with the port. A suitable surfaced loading area shall be provided by each airport at a convenient location with respect to such office space. Such loading area shall be reserved for the use of aircraft entering or clearing through the airport.

(f) International airports shall be open to all aircraft for entry and clearance purposes and no charge shall be made for the use of said airports for such purposes. However, in any case where an international airport authorizes any such aircraft to use such airport for the taking on or discharging of passengers or cargo, or as a base for other commercial operations or for private operations, this paragraph shall not be interpreted to mean that charges may not be made for such commercial or private use of such airport.

(g) All aircraft entering or clearing through an international airport shall receive the required servicing by airport personnel promptly and in the order of arrival or preparation for departure without discrimination. The charges made for such servicing shall in no case exceed the schedule of charges prevailing at the airport in question. A copy of said schedule of charges shall be posted in a conspicuous place at the office space provided for the use of Federal officials connected with the port.

(h) International airports shall adopt and enforce observance of such requirements for the operation of airports, including airport rules, as may be prescribed or recommended by the Federal Aviation Agency.

(i) Requirements in addition to all the foregoing may be imposed at a particular airport as the needs of the district or area to be served by the airport may demand.

§ 71.700 Appendix—Excerpts from International Sanitary Regulations (World Health Organization Regulations No. 2).

PART I—DEFINITIONS

Article 1

For the purposes of these Regulations—

* * * * *

"direct transit area" means a special area established in connexion with an airport, approved by the health authority concerned and under its direct supervision, for accommodating direct transit traffic and, in particular, for accommodating, in segregation, passengers and crews breaking their air voyage without leaving the airport;

* * * * *

"local area" means—

(a) The smallest area within a territory, which may be a port or an airport, having a defined boundary and possessing a health organization which is able to apply the appropriate sanitary measures permitted or prescribed by these Regulations; the situation of such an area within a larger area which also possesses such a health organization shall not preclude the smaller area from being a local area for the purposes of these Regulations; or (b) an airport in connexion with which a direct transit area has been established;

* * * * *

PART IV—SANITARY MEASURES AND PROCEDURES

* * * * *

CHAPTER II—SANITARY MEASURES ON DEPARTURE

Article 30

1. The health authority for a port or an airport or for the local area in which a frontier post is situated may, when it considers it necessary, medically examine any person before his departure on an international voyage. The time and place of this examination shall be arranged to take into account the customs examination and other formalities, so as to facilitate his departure and to avoid delay.

2. The health authority referred to in paragraph 1 of this Article shall take all practicable measures—

(a) To prevent the departure of any infected person or suspect;

(b) To prevent the introduction on board a ship, an aircraft, a train, or a road vehicle of possible agents of infection or vectors of a quarantinable disease.

3. Notwithstanding the provisions of subparagraph (a) of paragraph 2 of this Article, a person on an international voyage who on arrival is placed under surveillance may be allowed to continue his voyage. If he is doing so by air, the health authority for the airport shall record the fact on the General Declaration.

* * * * *

PART VI—SANITARY DOCUMENTS

Article 98

1. The certificates specified in Appendices 1, 2, 3, and 4 shall be printed in English and in French. An official language of the territory of issue may be added.

2. The certificates referred to in paragraph 1 of this Article shall be completed in English or in French.

Article 99

A vaccination document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in Appendix 2, 3, or 4 if—

(a) It embodies medical information substantially the same as that required by such form; and

(b) It contains a statement in English or in French recording the nature and date of the vaccination and to the effect that it is issued in accordance with this Article.

* * * * *

PART X—TRANSITIONAL PROVISIONS

* * * * *

Article 115

1. A certificate of vaccination issued in accordance with the Convention of 21 June 1926, as amended by the Convention of 15 December 1944, or in accordance with the Convention of 12 April 1933, as amended by the Convention of 15 December 1944, before the entry-into-force of these Regulations shall continue to be valid for the period for which it was previously valid. Moreover, the validity of a certificate of vaccination against yellow fever so issued shall be extended for two years after the date on which it would otherwise have ceased to be valid.

* * * * *

NOTE: Forms relating to International Sanitary Regulations filed as part of the original document.

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS [1]

Sec.
72.1 Definitions.
72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.
72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.
72.4 Notice of delivery; failure to receive.
72.5 Requirements; variations.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 42 U.S.C. 216; sec. 361, 58 Stat. 703, (42 U.S.C. 264).

SOURCE: 45 FR 48627, July 21, 1980, unless otherwise noted.

§ 72.1 Definitions.

As used in this part:

"Biological product" means a biological product prepared and manufactured in accordance with the provisions of 9 CFR Parts 102-104 and 21 CFR Parts 312 and 600-680 and which, in accordance with such provisions, may be shipped in interstate traffic.

"Diagnostic specimen" means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

"Etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease.

"Interstate traffic" means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

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[1] The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

§ 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

§ 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of § 72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

BACTERIAL AGENTS

Acinetobacter calcoaceticus.
Actinobacillus—all species.
Actinomycetaceae—all members.
Aeromonas hydrophila.
Arachnia propionica.
Arizona hinshawii—all serotypes.
Bacillus anthracis.
Bacteroides spp.
Bartonella—all species.
Bordetella—all species.
Borrelia recurrentis, B. vincenti.
Brucella—all species.
Campylobacter (Vibrio) foetus, C. (Vibrio) jejuni.
Chlamydia psittaci, C. trachomatis.
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.
Edwarsiella tarda.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella (Pasteurella) Tularensis.
Haemophilus ducreyi, H. influenzae.
Klebsiella—all species and all serotypes.
Legionella—all species and all Legionella-like organisms.
Leptospira interrogans—all serovars.
Listeria—all species.
Mimae polymorpha.
Moraxella—all species.
Mycobacterium—all species.
Mycoplasma—all species.
Neisseria gonorrhoeae, N. meningitidis.
Nocardia asteroides.
Pasteurella—all species.
Plesiomonas shigelloides.
Proteus—all species.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Salmonella—all species and all serotypes.
Shigella—all species and all serotypes.
Sphaerophorus necrophorus.
Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pneumoniae.
Streptococcus pyogenes.
Treponema careteum, T. pallidum, and *T. pertenue.*
Vibrio cholerae, V. parahemolyticus.
Yersinia (Pasteurella) pestis, Y. enterocolitica.

FUNGAL AGENTS

Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.

VIRAL AND RICKETTSIAL AGENTS

Adenoviruses—human—all types.
Arboviruses—all types.
Coxiella burnetii.
Coxsackie A and B viruses—all types.
Creutzfeldt—Jacob agent
Cytomegaloviruses.
Dengue viruses—all types.
Ebola virus.
Echoviruses—all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
Herpesvirus—all members.
Infectious bronchitis-like virus.
Influenza viruses—all types.
Kuru agent.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses—all types.
Polioviruses—all types.
Poxviruses—all members.

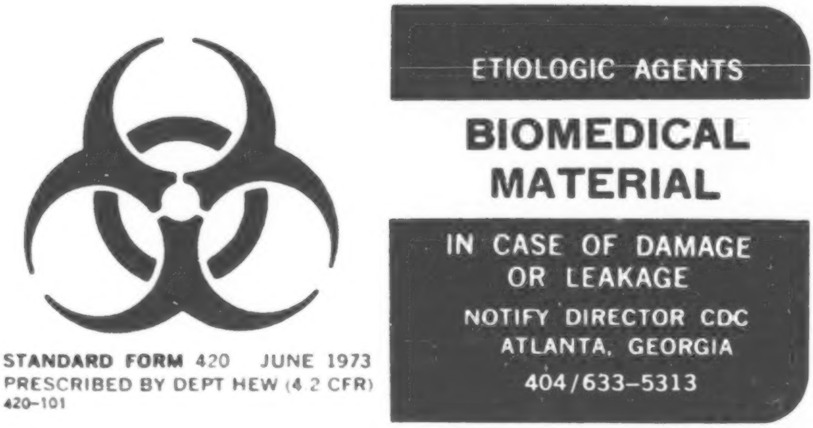
Rabies virus—all strains.
Reoviruses—all types.
Respiratory syncytial virus.
Rhinoviruses—all types.
Rickettsia—all species.
Rochalimaea quintana.
Rotaviruses—all types.
Rubella virus.
Simian virus 40.
Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
Vaccinia virus.
Varicella virus.
Variola major and Variola minor viruses.
Vesicular stomatis viruses—all types.
White pox viruses.
Yellow fever virus.[2]

(a) *Volume not exceeding 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

(b) *Volume greater than 50 ml.* Packaging of material in volumes of 50 ml. or more shall comply with requirements specified in paragraph (a) of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(c) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(d)(1) The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:



ETIOLOGIC AGENTS
BIOMEDICAL
MATERIAL
IN CASE OF DAMAGE
OR LEAKAGE
NOTIFY DIRECTOR CDC
ATLANTA, GEORGIA
404/633-5313

STANDARD FORM 420 JUNE 1973
PRESCRIBED BY DEPT HEW (42 CFR)
420-101

(2) The color of material on which the label is printed must be white, the symbol red, and the printing in red or white as illustrated.

(3) The label must be a rectangle measuring 51 millimeters (mm) (2 inches) high by 102.5 mm (4 inches) long.

(4) The red symbol measuring 38 mm (1½ inches) in diameter must be centered in a white square measuring 51 mm (2 inches) on each side.

(5) Type size of the letters of label shall be as follows:

Etiologic agents—10 pt. rev.
Biomedical material—14 pt.
In case of damage or leakage—10 pt. rev.
Notify Director CDC, Atlanta, Georgia—8 pt. rev.
404-633-5313—10 pt. rev.

(e) *Damaged packages.* The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing an Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333, by telephone: (404) 633-5313. The carrier shall also notify the sender.

(f) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery:

Coccidioides immitis.
Ebola virus.
Francisella (Pasteurella) tularensis.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Herpesvirus simiae (B virus).
Histoplasma capsulatum.
Lassa virus.
Marburg virus.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk Hemorrhagic fever, and Central European encephalitis viruses, Variola minor, and Variola major.
Variola major, Variola minor, and Whitepox viruses.
Yersinia (Pasteurella) pestis.[1]

§ 72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain or reasonably believed to contain etiologic agents listed in § 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 (telephone (404) 633-5313).

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[1] This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be transported in accordance with requirements contained in § 72.3(f).

§ 72.5 Requirements; variations.

The Director, Center for Disease Control, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

PART 74—CLINICAL LABORATORIES

Subpart A—Definitions and Applicability

Sec.
74.1 Definitions.
74.2 Applicability.

Subpart B—License: Applications and Issuance

74.10 License application.
74.11 Issuance or renewal of license.
74.12 Repetitious applications.

Subpart C—Quality Control

74.20 General.
74.21 Microbiology.
74.22 Serology.
74.23 Clinical chemistry.
74.24 Immuno-hematology.
74.25 Hematology.
74.26 Exfoliative cytology; histopathology; oral pathology.
74.27 Radiobioassay.

Subpart D—Personnel Standards

74.30 General applicability of regulations prescribed under Title 20, Code of Federal Regulations.
74.31 Exceptions and additions.

Subpart E—Proficiency Testing

74.40 Procedures; samples; test conditions.
74.41 Reference laboratories; referee laboratories.
74.42 Satisfactory participation; particular procedures and categories.
74.43 Test results.

Sec.

Subpart F—Accreditation-State Laws-Stringency of Standards-Termination

74.46 Accredited laboratories; State laws; stringency of standards; letter of exemption.
74.47 Accreditation; stringency of standards; failure to demonstrate; applicability of licensing requirements.

Subpart G—General Provisions

74.50 Records: Maintenance, availability, retention.
74.51 Reports to the Secretary.
74.52 Personnel records.
74.53 Specimen records.
74.54 Laboratory report and record.
74.55 Equipment and facilities.
74.56 Inspection.
74.57 Change in ownership.
74.58 Change in director or supervisor.

Subpart H—Revocation, Suspension, and Limitation of Licenses and Letters of Exemption; Notice

74.60 Revocation, suspension, and limitation of licenses and letters of exemption.
74.61 Contents of notice.

Subpart I—Hearings [Reserved]

AUTHORITY: Sec. 215, 58 Stat. 690; 42 U.S.C. 216.

SOURCE: 33 FR 20043, Dec. 31, 1968, unless otherwise noted.

Subpart A—Definitions and Applicability

§ 74.1 Definitions.

(a) As used in this part, all terms not defined herein shall have the meaning given them in the Act.

(b) "Accredited institution" means an institution accredited by an agency or organization recognized for such purpose by the U.S. Commissioner of Education.

(c) "Accredited laboratory" means a laboratory, or a laboratory in a hospital, accredited by an approved accreditation body.

(d) "Act" means the Public Health Service Act, as amended, 42 U.S.C. 201, et seq.

(e) "Approved accreditation body" means, with respect to hospitals, Joint Commission on the Accreditation of Hospitals, or American Osteopathic

Association, and with respect to laboratories, Commission on Inspection and Accreditation of the College of American Pathologists; or any other national accreditation body which has been approved by the Secretary as provided in section 353 of the Act.

(f) "Director" means the Director of the National Communicable Disease Center, Health Services and Mental Health Administration, Department of Health and Human Services.

(g) "Health insurance program" means the program created under Title XVIII of the Social Security Act, pursuant to which individuals are entitled to have payments made on their behalf for services performed by independent laboratories as provided in 20 CFR Part 405,[1] Subpart M.

(h) A "physician" is a person licensed to practice medicine or osteopathy in any state or possession of the United States.

(i) "Radiobioassay" includes (1) an examination to identify radionuclides or determine and quantitate body levels of radionuclides which are taken in by chronic or acute absorption, ingestion, or inhalation and (2) following the administration of a radioactive material to a patient, the subsequent analysis of a body fluid or excreta in order to evaluate body function.

(j) A "referee laboratory" is a laboratory designated by the Secretary to examine specimens or other materials for purposes of proficiency testing using the same time schedule allowed for licensed laboratories and under conditions similar to those under which licensed laboratories examine materials.

(k) A "reference laboratory" is a laboratory designated by the Secretary to authenticate the identification, content, and titer of samples and other materials used or to be used in proficiency testing.

(l) "Secretary" means the Secretary of Health and Human Services or his designee.

(m) "Specimen" means any material derived from the human body for examination or other procedure for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man.

[33 FR 20043, Dec. 31, 1968, as amended at 38 FR 10721, May 1, 1973]

§ 74.2 Applicability.

(a) Except as otherwise provided herein, the regulations in this part apply to laboratories engaged in the laboratory examination of, or other laboratory procedures relating to, specimens solicited or accepted in interstate commerce directly or indirectly, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health, of man.

(b) The regulations in this part do not apply to the following:[1]

(1) Any laboratory with respect to any category in which it accepts no more than 100 specimens during any calendar year: *Provided*, That the laboratory holds an unrevoked and unsuspended letter of exemption for such category issued upon application submitted by such laboratory to the Director, National Communicable Disease Center, 1600 Clifton Road NE., Atlanta, Ga. 30333, and upon its agreement to maintain and make available such accession and other records, submit such information and reports, and comply with such provisions of this part as the Secretary may reasonably find necessary to determine its initial and continuing eligibility for exemption under this paragraph. For purposes of this paragraph, a category shall be one of the following: (i) Microbiology and serology; (ii) clinical chemistry; (iii) immunohematology; (iv) hematology; (v) pathology; (vi) radiobioassay.

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[1] Redesignated as 42 CFR Part 405 at 42 FR 52826, Sept. 30, 1977.

[1] The coverage of services of independent laboratories under section 1861 of the Social Security Act, as amended, 42 U.S.C. 1395x, is subject to the provisions of Title 20, Code of Federal Regulations, Part 405,[redesignated as 42 CFR Part 405] and the regulation of biological products under section 351 of the Public Health Service Act, as amended, 42 U.S.C. 262, is subject to the provisions of Title 42, Code of Federal Regulations, Part 73.

(2) Pursuant to section 353(i), any clinical laboratory operated by a licensed physician, osteopath, dentist, or podiatrist, or group thereof, who performs or perform laboratory tests or procedures solely as an adjunct to the treatment of his or their patients.

(3) Pursuant to section 353(i), any laboratory with respect to tests or other procedures made by it for any person engaged in the business of insurance if made solely for the purposes of determining whether to write an insurance contract or of determining eligibility or continued eligibility for payments thereunder.

(4) Clinical laboratories exempted by the Secretary pursuant to section 353(l) of the Act.

(c) The requirements of this part for the issuance and renewal of licenses do not apply to an accredited laboratory: *Provided*, That the Secretary finds that the standards applied by the accrediting body are equal to or more stringent than the provisions of the Act and of this part and there is adequate provision for assuring that such standards continue to be met by such hospital and such laboratory: *Provided further*, That the laboratory holds an unrevoked and unsuspended letter of exemption issued pursuant to § 74.46.

[33 FR 20043, Dec. 31, 1968, as amended at 35 FR 6177, Apr. 16, 1970]

Subpart B—License: Applications and Issuance

§ 74.10 License application.

(a) An application for the issuance or renewal of a license for a laboratory applicable to one or more laboratory procedures or categories of laboratory procedures for which standards are set out herein may be made to the Director by the owner, operator or authorized representative of such laboratory.

(b) The application shall be made on a form or forms prescribed by the Secretary, signed by the owner, operator, or by an authorized representative, and shall contain or be accompanied by such information, agreements and data as the Secretary may require, including an agreement that the applicant will operate the laboratory in accordance with standards which have been prescribed by the Secretary to carry out the purposes of the Act.

(c) A separate application must be filed for each laboratory location.

(d) [Reserved]

(e) Licenses shall be issued to be applicable to one or more of the following procedures or categories of procedures except upon application for a limited license approved by the Secretary:

(1) Microbiology and serology:

(i) Bacteriology.

(ii) Mycology.

(iii) Parasitology.

(iv) Virology.

(v) Serology (syphilis).

(vi) Serology (nonsyphilis).

(2) Clinical chemistry:

(i) Blood and cerebrospinal fluid chemistry.

(ii) Endocrinology.

(iii) Toxicology.

(iv) Urinalysis.

(3) Immuno-hematology.

(4) Hematology.

(5) Pathology:

(i) Exfoliative cytology.

(ii) Histopathology.

(iii) Oral pathology.

(6) Radiobioassay.

(f) An application for the renewal of a license shall be submitted not less than 30 days nor more than 60 days prior to the expiration of the period for which the license was issued.

[33 FR 20043, Dec. 31, 1968, as amended at 45 FR 26960, Apr. 22, 1980]

§ 74.11 Issuance or renewal of license.

(a) If, after a review of the application and such additional information as the Secretary may require and an on site inspection of the laboratory premises with respect to which the license is sought, the Secretary is satisfied that such laboratory will be operated in accordance with the standards and other requirements of the Act and of this part and will provide consistent performance of accurate laboratory procedures and services, he shall issue an initial or renewal license with respect to such laboratory applicable to laboratory procedures or categories of procedures as specified therein.

(b) Such initial or renewal license shall be issued for a term of 1 year.

(c) If the Secretary determines that the application for the issuance or renewal of a license shall not be granted in whole or in part, he will, prior to denial of such application, give reasonable notice and opportunity for a hearing as provided herein to the applicant and a statement of the grounds on which it is proposed to deny the application or any part thereof.

§ 74.12 Reptitious applications.

Where an application for a license has been denied in whole or in part, or a license has been revoked or limited, an application for a license to be applicable to procedures or categories of procedures affected by such adverse action made by or on behalf of the same applicant or licensee, shall not be accepted for consideration until after 1 year from the effective date of the adverse action: *Provided*, That upon good cause found, the Secretary may waive the application of this section.

Subpart C—Quality Control

§ 74.20 General.

Quality controls imposed and practiced by the laboratory must provide for and assure:

(a) Preventive maintenance, periodic inspection and testing for proper operation of equipment and instruments, as may be appropriate; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial action to be taken in response to detected defects.

(b) Adequacy of facilities, equipment, instruments, and methods for performance of the procedures or categories of procedures for which a license application is filed or granted; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature controlled spaces and equipment, including water baths, incubators, sterilizers, and refrigerators, to assure proper performance; evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics.

(c) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength, or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information. Materials of substandard reactivity and deteriorated materials may not be used.

(d) The availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category (e.g., clinical chemistry, hematology, and pathology), of current laboratory manuals or other complete written descriptions and instructions relating to (1) the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews, (2) reagents, (3) control and calibration procedures, and (4) pertinent literature references. Text books may be used as supplements to such written descriptions but may not be used in lieu thereof.

(e) Written approval by the director or supervisor of all changes in laboratory procedures.

(f) Maintenance and availability to laboratory personnel and to the Secretary of records reflecting dates, and where appropriate the nature, of inspection, validation, remedial action, monitoring, evaluation, and changes and dates of changes in laboratory procedures.

(g) Solicitation designed to provide for collection, preservation, and transportation of specimens sufficiently stable to provide accurate and precise results suitable for clinical interpretation.

[33 FR 20043, Dec. 31, 1968, as amended at 38 FR 10721, May 1, 1973]

§ 74.21 Microbiology.

Chemical and biological solutions, reagents, and antisera shall be tested and inspected each day of use for reactivity and deterioration.

(a) *Bacteriology and mycology.* Staining materials shall be tested for intended reactivity by concurrent application to smears of microorganisms with predictable staining characteristics. Each batch of medium shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, and biochemical response.

(b) *Parasitology.* A reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.

(c) *Virology.* Systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the entire range of viruses which are etiologically related to clinical diseases for which services are offered. Records shall be maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.

[33 FR 20043, Dec. 31, 1968, as amended at 38 FR 10722, May 1, 1973]

§ 74.22 Serology.

(a) Serologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components (antigens, complement, erythrocyte indicator systems, etc.), shall be employed to insure reactivity and uniform dosage. Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

(b) Each new lot of reagent shall be tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.

(c) Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "Manual of Tests for Syphilis 1969," USPHS Publication No. 411, January 1969.[1]

§ 74.23 Clinical chemistry.

(a) Each procedure shall be recalibrated or rechecked at least once on each day of use. Records shall be maintained and be available to laboratory personnel and the Secretary which document the routine precision of each method, automated or manual, and its recalibration schedule. At least one standard and one reference sample (control) shall be included with each run of unknown specimens where such standards and reference samples are available. Control limits for standards and reference samples shall be recorded and displayed and shall include the course of action to be instituted when the results are outside the acceptable limits.

(b) Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference samples.

§ 74.24 Immuno-hematology.

(a) ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums licensed under Part 73, Title 42, Code of Federal Regulations, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. For confirmation of ABO grouping, the unknown serum shall be tested with known A_1andB red cells.

(b) The potency and reliability of reagents shall be checked each day of use.

(c) The $Rh_0(D)$ type shall be determined by testing unknown red cells with anti-Rh_0(anti-D) typing serum licensed under Part 73, Title 42, Code of Federal Regulations, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. Anti-Rh_0'(CD), anti-Rh_0''(DE), and anti-$Rh_0rh'rh''$(CDE) serums licensed pursuant to Part 73, Title 42, Code of Federal Regulations, or possessing an equivalent potency may be used for typing donor blood. All Rh_0 negative donor and patient cells shall be tested for the Rh_0 variant (D^2). A control system of patient's cells suspended in his own serum or in albumin shall be employed when the test is performed in a protein medium.

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[1] Obtainable from U.S. Government Printing Office.

(d) Rh$_o$(D) positive and negative control tests shall be used for each test system employed to check the reactivity of the anti-Rh$_o$(D) serum each day of use. Reactivity of known red cells used for antibody screening shall be tested each day of use with a suitable positive and negative control. The reactivity of anti-human globulin reagents (Coombs' serum) shall be tested each day of use and whenever a new lot of reagent is used.

§ 74.25 Hematology.

Instruments and other devices used in hematological examination of specimens shall be recalibrated or retested or reinspected, as may be appropriate, each day of use. Each procedure for which standards and controls are available shall be recalibrated or rechecked each day of use with standards or controls covering the entire range of expected values. Tests such as the one-stage prothrombin time test shall be run in duplicate unless the laboratory can demonstrate that low frequency of random error or high precision makes such testing unnecessary. Reference materials, such as hemoglobin pools, and stabilized cells, shall be tested at least once each day of use to insure accuracy of results. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by random replicate testing of specimens. The accuracy and precision of blood cell counts and hematocrit and hemoglobin measurements shall be tested each day of use.

§ 74.26 Exfoliative cytology; histopathology; oral pathology.

(a) *Exfoliative cytology.* The laboratory director or supervisor qualified in cytology or cytotechnologist shall rescreen for proper staining and correct interpretation at least a 10-percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel not possessing director or supervisor qualifications. All gynecological smears interpreted to be in the "suspicious" or positive categories by screeners shall be confirmed by the laboratory director or qualified supervisor, and the report shall be signed by a physician qualified in pathology or cytology. All nongynecological cytological preparations, positive and negative, shall be reviewed by a director or supervisor qualified in cytology. Nonmanual methods shall provide quality control similar to that provided in other nonmanual laboratory procedures. All smears shall be retained for not less than 2 years from date of examination.

(b) *Histopathology and oral pathology.* All special stains shall be controlled for intended reactivity by use of positive slides. Stained slides shall be retained for not less than 2 years from date of examination and blocks shall be retained for not less than 1 year from such date. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

§ 74.27 Radiobioassay.

The counting equipment shall be checked for stability at least once on each day of use, with radioactive standards or reference sources. Reference samples with known activity and within expected levels of normal samples, shall be processed in replicate quarterly. For each method, records shall be maintained and be available to staff and to the Secretary which document the routine precision and the recalibration schedule.

Subpart D—Personnel Standards

§ 74.30 General applicability of regulations prescribed under Title 20,[1] Code of Federal Regulations.

Except as otherwise provided herein, the standards for qualifications of the director and other personnel and for competency to perform procedures are the standards prescribed in §§ 405.1312, 405.1313, 405.1314, and 405.1315(a)(b), Title 20,[1] Code of Federal Regulations, for coverage of services of independent laboratories.

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[1] Redesignated as 42 CFR Part 405 at 42 FR 52826, Sept. 30, 1977.

§ 74.31 Exceptions and additions.

For purposes of meeting the requirements of this part—

(a) The exception specified in 20 CFR 405.1312(b)(4)[1] for the period ending June 30, 1971, may be made if (1) the conditions prescribed therein are met or (2) if the director was responsible for the direction of a clinical laboratory for 12 months within the 5 years preceding January 1, 1968, if the conditions prescribed in 20 CFR 405.1312(b)(4)(i)(*a*)-(*c*)[1] are met and if the laboratory meets the applicable proficiency standards prescribed in this part.

(b) The director who qualified under paragraph (a) of this section, may continue to qualify after June 30, 1971—

(1) If the conditions specified in 20 CFR 405.1312(b)(5)[1] are met; or

(2) (i) If the laboratory he directs meets the standards prescribed in this part and (ii) the laboratory which he directs meets the standards for proficiency prescribed herein for at least one year in the period between the effective date of these regulations and July 1, 1971, and annually thereafter in all the specialties or subspecialties for which the laboratory is licensed except that if the director first qualifies under paragraph (a) of this section after December 31, 1968, but before July 1, 1971, the period referred to above in paragraph (b)(2)(ii) of this section shall begin on the date he first qualified and the laboratory he directs, if otherwise meeting the standards in this part, shall be deemed to meet the standards as required in this subdivision beginning with the date the director so qualified.

(c) The requirement specified in 20 CFR 405.1313(a)(1)[1] for the presence of a general supervisor on the laboratory premises during all hours in which tests are being performed shall not be applicable to the performance of procedures required for emergency purposes provided that the person performing the test is qualified under this part to perform the examination and the results of his work are reviewed by the supervisor or director during his next duty period.

(d) The exception specified in 20 CFR 405.1313(b)(5)[1] may be made if (1) the conditions prescribed therein are met or (2) if the supervisor was performing the duties of a clinical laboratory supervisor on January 1, 1968, or between July 1, 1961, and January 1, 1968, and has had at least 15 years of pertinent laboratory experience prior to January 1, 1968 (the required years of experience may be reduced as provided in such 20 CFR 405.1313(b)(5)).[1]

(e) The supervisor who meets the requirements under paragraph (d) of this section may continue to qualify after June 30, 1971—

(1) If the conditions specified in 20 CFR 405.1313(b)(6)[1] are met; or

(2) If the conditions specified in 20 CFR 405.1313(b)(6)[1] are met except that (i) the required 2-year period for the performance of the duties of a supervisor may be either between July 1, 1966, and July 1, 1971, or during the 15 years prior to January 1, 1968, he acquired pertinent experience as specified in paragraph (d) of this section, and (ii) where qualifying years in a laboratory described in 20 CFR 405.1313(b)(6) (i) or (ii)[1] are obtained after the effective date of these regulations, the laboratory may be a laboratory which meets applicable conditions prescribed either in this part or under the health insurance program.

(f) If the factor in 20 CFR 405.1314(b)(1)[1] is not met and the laboratory performs tests in serology, the director or a supervisor (1) must hold an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution, or be a physician and (2) subsequent to graduation have had at least 4 years' experience in serology.

(g) If the laboratory performs tests in radiobioassay, the director or a supervisor must be a physician or must hold an earned doctoral or master's degree in chemical, physical, or biological sciences from an accredited institution and subsequent to graduation must have at least 1 year of experience in radiobioassay.

(h) The exception specified in 20 CFR 405.1315(b)(5)[1] for the period ending June 30, 1971, may be made (1) if the conditions prescribed therein are met or (2) if the technologist was performing the duties of a clinical laboratory technologist on January 1, 1968, or between July 1, 1961, and January 1, 1968, and has had at least 10 years of pertinent clinical laboratory experience prior to January 1, 1968 (the required years of experience may be reduced as provided in such 20 CFR 405.1315(b)(5)).[1]

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[1] Redesignated as 42 CFR Part 405 at 42 FR 52826, Sept. 30, 1977.

(i) The technologist who meets the requirements under paragraph (h) of this section may continue to qualify after June 30, 1971—

(1) If the conditions specified in 20 CFR 405.1315(b)(6)[1] are met; or

(2) If the conditions specified in 20 CFR 405.1315(b)(6)[1] are met except that (i) the required 2-year period for the performance of the duties of a clinical laboratory technologist may be either between July 1, 1966, and July 1, 1971, or during the 10 years he acquired pertinent experience as specified in paragraph (h) of this section and (ii) where qualifying years in a laboratory described in 20 CFR 405.1315(b)(6) (i) or (ii)[1] are obtained after the effective date of these regulations, the laboratory may be a laboratory which meets applicable conditions prescribed either in this part or under the health insurance program.

(j) Each cytotechnologist shall possess a current license as a cytotechnologist issued by the State, if such licensing exists, and (1) shall have successfully completed 2 years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences and must have received 12 months of training in a school of cytotechnology approved by the American Medical Association, or (2) received 6 months of formal training in a school of cytotechnology approved by the American Medical Association and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal 6 months of training, or (3) prior to January 1, 1969, shall have been graduated from high school, completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed 2 years of full-time experience in cytotechnology.

(k) Where an individual who does not meet the requirements specified herein for a technologist is engaged in performing repetitive prcedures only, which require a limited exercise of independent judgment, he may perform such procedures only under the personal and direct supervision of a technical supervisor as defined in 20 CFR 405.1314(b) (1) through (8)[1] or a technologist as defined in 20 CFR 405.1315(b) (1) through (4).[1]

[33 FR 20043, Dec. 31, 1968, as amended at 34 FR 13277, Aug. 15, 1969]

Subpart E—Proficiency Testing

§ 74.40 Procedures; samples; test conditions.

All applicants and licensees shall be subject to proficiency testing, as directed by the Secretary, to aid in assessing the competency of laboratory staff and the adequacy and quality of facilities, equipment, reagents, working conditions, and procedures. Such testing may be carried out during onsite inspections or by submittal to laboratories of samples for examination. Regularly assigned personnel must examine samples using the laboratory's routine methods. The laboratory shall be tested only in those procedures or categories of procedures for which a license application, original or renewal, has been filed with the Secretary or for which the Secretary has issued a license. The samples to be tested may be provided prior to, during, or subsequent to, inspections. The time allowed for testing will be the time required, as determined by the Secretary, under conditions of normal laboratory operation. Laboratory personnel shall enter the date and time of receipt of samples, results of tests, and such other information as the Secretary may require, on forms provided or required by the Secretary.

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[1] Redesignated as 42 CFR Part 405 at 42 FR 52826, Sept. 30, 1977.

§ 74.41 Reference laboratories; referee laboratories.

(a) Samples identical to those submitted to laboratories for proficiency testing in categories of procedures which require quantitative results to be established where there is a continuum of results possible shall be submitted to 10 or more reference laboratories for analysis. These samples may be submitted to the reference laboratories for analysis pursuant to the same time schedule and under conditions similar to those to which the laboratories being tested will be subjected.

(b) Samples identical to those submitted to laboratories for proficiency testing in categories of procedures which require semiquantitative or qualitative results, shall be submitted to three or more reference laboratories which shall examine the material contained in the sample in detail and report identification and content or titer to the Secretary. Samples identical to those submitted to laboratories for proficiency testing shall also be submitted to 10 or more referee laboratories for examination pursuant to the same time schedule and under conditions similar to those to which the laboratories being tested will be subjected.

§ 74.42 Satisfactory participation; particular procedures and categories.

(a) *Clinical chemistry; hematology.* (1) The limits for acceptability of results for each analysis shall be obtained by superimposing, on one scale, three subsets of limits obtained as provided in paragraph (a)(2) of this section.

(2) (i) *Subset—Applicant and licensee laboratories.* The subset of limits for applicant and licensee laboratories shall encompass the central 95 percent tile calculated from the results of all applicant and licensee laboratories. A reported result which is obviously deviant from the other results will not be used in determining the limits. However, for any sample, no more than 5 percent of the results will be discarded on the basis of being "obivously deviant."

(ii) *Subset—Reference laboratories.* The subset of limits determined from reference laboratory results shall encompass all reference laboratory results and shall consist of the lowest and highest result. A result which is obviously deviant from the other results will not be used in establishing the limits. However, for any sample, no more than 5 percent of the results will be discarded on the basis of being "obviously deviant."

(iii) *Subset—Clinical requirements.* The subset of limits for clinical requirements shall be centered on the median reference laboratory result on each sample and shall encompass 0.5 (one-half) the normal population range, in the case of a sample the value of which is in the normal range, or shall encompass 0.5 (one-half) the appropriate range in the case of a sample the value of which is outside the normal range. The normal population range or other appropriate range shall be determined by the Secretary.

(3) Results for applicant and licensee laboratories must fall between the lowest lower limit and highest upper limit of the three subsets of limits.

(b) *Microbiology.* The results obtained by applicant, licensee, and referee laboratories from tests on samples shall be graded by comparison with the results obtained by reference laboratories. The grade of an applicant or licensee laboratory may not be more than 10 percentage points lower than the minimal grade obtained by the referee laboratories. A grade obtained by a referee laboratory which is obviously deviant from those obtained by other referee laboratories will not be used in establishing acceptable achievement. However, for any shipment of samples the grades of not more than ten percent of the referee laboratories will be discarded on the basis of being "obviously deviant."

(c) *Serology.* (1) The results obtained by applicant and licensee and reference laboratories from qualitative and quantitative tests on samples shall be graded by, (i) comparing them with results obtained by reference laboratories, and (ii) comparing results of duplicate samples.

(2) Agreement with reference laboratories:

(i) The grade for the qualitative test shall be the percentage of results in agreement with the results obtained by the reference laboratories.

(ii) The grade for the quantitative test shall be the percentage of results in agreement: *Provided*, That results shall be deemed to be in agreement where each result (titer) does not deviate more than one twofold dilution from the range of results obtained by the reference laboratories.

(iii) Grades must fall, and deviant results shall be treated, as provided in paragraph (b) of this section for microbiology.

(3) Reproducibility on duplicate specimens:

(i) The grade for the qualitative tests shall be the percentage of results on duplicate specimens that are in agreement.

(ii) The grade for the quantitative test shall be the percentage of results on duplicate specimens that are in exact agreement or that reflect a deviation of not more than one fourfold dilution for nonsyphilis serological tests; or one twofold dilution for syphilis serological tests.

(iii) Grades must fall, and deviant results will be treated, as provided in paragraph (b) of this section for microbiology.

(d) *Immunohematology.* For ABO grouping, Rh-typing, and cross-matching, there must be agreement with the results of the tests made by reference laboratories. For irregular antibody identification, the criteria contained in paragraph (c) of this section, relating to proficiency testing in serology, shall be applicable.

(e) *Exfoliative cytology; histopathology; oral pathology.* The results obtained by applicant and licensee laboratories and referee laboratories from examination of histopathological sample specimens shall be graded by comparison with the results obtained by reference laboratories which are directed by a Board Certified pathologist. The lowest acceptable grade of an applicant and licensee laboratory must fall within 10 percentage points of the minimal grade obtained by the referee laboratories. The results obtained by applicant and licensee laboratories and referee laboratories from examination of cytological specimens shall be graded by comparison with the results obtained by reference laboratories which are directed by a Board certified pathologist or certified cytopathologist. The lowest acceptable cancer detection performance of applicant and licensee laboratories must fall within 10 percentage points of the minimum grade obtained by the referee laboratories. A result obtained by a referee laboratory which is obviously deviant from those obtained by reference and other referee laboratories will not be used in establishing acceptable achievement. However, for any shipment of samples, no more than 10 percent of the referee laboratories' grades will be discarded on the basis of being "obviously deviant."

(f) *Radiobioassay.* The limits for acceptability of results for each analysis shall be determined by the central 95 percentile calculated from the results of all laboratories. A reported result which is obviously deviant from the other results will not be used in determining the limits. However, for any sample, no more than 5 percent of the results will be discarded on the basis of being obviously deviant: *Provided*, That no result may be considered unsatisfactory if it falls within the limits established by reference laboratories.

[33 FR 20043, Dec. 31, 1968, as amended at 38 FR 10722, May 1, 1973]

§ 74.43 Test results.

The Secretary shall notify the laboratory director of the results of the proficiency tests. Where the laboratory reports reflect lack of proficiency, the Secretary may recommend corrective measures, consultation, or training in an appropriate laboratory; and may upon the written request of the laboratory director, furnish the laboratory with additional samples after corrective measures have been taken. Results reflecting a lack of proficiency may constitute a basis for denial, revocation, suspension, or limitation of the laboratory license or letter of exemption.

Subpart F—Accreditation–State Laws–Stringency of Standards–Termination

§ 74.46 Accredited laboratories; State laws; stringency of standards; letter of exemption.

(a) *Accredited laboratories; State laws; stringency of standards; assurance of continuation of compliance with standards.* In determining whether the standards applied by an approved accreditation body in inspecting and accrediting any hospital or any laboratory pursuant to the provisions of section 353(d)(2) of the Act or provided for by State law under section 353(l), are equal to or more stringent than the provisions of the Act and the rules and regulations issued pursuant thereto, the Secretary may consider inter alia whether the standards applied or provided for are equal to or more stringent than those applicable or issued hereunder relating to maintenance of a quality control program, records, equipment, and facilities, qualifications of personnel, quality and extent of proficiency testing, renewal of accreditation and frequency and comprehensiveness of on-site inspections. The standards for accreditation of laboratories shall be sumitted in writing to, and reviewed by, the Secretary at least annually and from time to time as the Secretary may deem necessary: *Provided,* That neither the number of tests, nor the number of inspections required or provided for by the standards of such body or the law of a State shall be conclusive in determining whether such standards are equal to or more stringent than those required by section 353 of the Act and the standards prescribed thereunder or whether there is adequate provision for assuring that such standards continue to be met.

(b) *Accreditation; notices; submittal.* An approved accreditation body shall submit to the Director written notice of—

(1) Accreditation of each hospital or laboratory accredited by it (unless the laboratory is a laboratory to which the regulations contained herein are not applicable under the provisions of § 74.2(b)), containing the name of such hospital or laboratory, the date or dates of such accreditation, and the procedures to which such accreditation is applicable, within 10 days after (i) receipt of notice from the Secretary that the standards applied by such body have been determined to be equal to or more stringent than the provisions of section 353 of the Act and the rules and regulations issued under such section 353, or (ii) the date of accreditation, whichever is later.

(2) Termination of accreditation of a hospital or laboratory within 5 days after such termination.

(3) Results of proficiency tests conducted by the approved accreditation body as soon as they become available and in no event, except upon written authorization from the Secretary, later than 60 days after the date designated for submittal of results to the accrediting body.

(c) *Letter of exemption; issuance.* The Secretary may issue a letter of exemption to a laboratory upon application by such laboratory, certifying to or providing on a form prescribed by the Secretary—

(1) Its accreditation by an approved accreditation body; the procedures to which such accreditation is applicable; and the date or dates of such accreditation.

(2) Its agreement to permit inspection by the Secretary, make records available and submit reports as may be required by the Secretary.

(3) Such other relevant information as the Secretary may require.

§ 74.47 Accreditation; stringency of standards; failure to demonstrate; applicability of licensing requirements.

(a) Standards of accrediting body; equivalence or greater stringency; failure to demonstrate: If the Secretary at any time, on the basis of (1) a review of the standards applied by an accrediting body, (2) evidence of violations of such standards, (3) inspections, or (4) other relevant factors, determines that the standards applied by an accrediting body are not equal to or more stringent than the provisions of section 353 of the Act and the rules and regulations issued thereunder or that the provision of any such body for requirements, practices, and procedures for assuring that such standards continue to be met by accredited hospitals and laboratories is inadequate, the Secretary shall give notice thereof to such accrediting body and shall provide a reasonable period for revision of standards, requirements, practices, and procedures and for submittal to the Director of satisfactory evidence (i) that it has adopted and effectively applied equivalent or more stringent standards to hospitals and laboratories in determining whether to accredit such hospitals and laboratories and (ii) that there is adequate provision for assuring that such standards continue to be met by the accredited hospitals or laboratories. Upon expiration of such period and notice to such body of the determination that it has not submitted satisfactory evidence, which notice shall contain a specification of the basis for the determination, the provisions of section 353 of the Act requiring licensing shall apply effective 30 days after the date of receipt of such notice by such accreditation body.

(b) Accreditation: *Inspection.* No exemption shall be granted unless the Secretary has received an agreement on forms prescribed by the Secretary signed by the owner or authorized representative of such laboratory to permit inspections as prescribed in this part for licensed laboratories.

(c) Accredited laboratories shall be subject to such provisions of the regulations in this part, including but not limited to those relating to proficiency testing and availability of records, as the Secretary may direct: Other than the provisions relating to licensing.

[33 FR 20043, Dec. 31, 1968, as amended at 38 FR 10722, May 1, 1973]

Subpart G—General Provisions

§ 74.50 Records: Maintenance, availability, retention.

Records of observations shall be made, concurrently with the performance, of each step in the examination of specimens. Records shall reflect the actual results of all control procedures. All pertinent laboratory records shall be made available for such inspection, examination, and copying as the Secretary may direct. All records shall be retained for a period of at least 2 years after the date of submittal of report except as otherwise prescribed in this part or authorized by the Secretary.

§ 74.51 Reports to the Secretary.

Laboratories shall submit to the Secretary such reports of operations as the Secretary, from time to time, may require.

§ 74.52 Personnel records.

Personnel records shall be maintained on a current basis. They shall include a complete resume of each employee's training, experience, duties, and date or dates of employment.

§ 74.53 Specimen records.

Daily accession records shall contain the following information:

(a) The laboratory number or other identification.

(b) The name and other identification of the person from whom the specimen was taken, if available.

(c) The name of the licensed physician or other person or laboratory who or which submitted the specimen.

(d) The date the specimen was collected by the physician, or other authorized person if available.

(e) The date the specimen was received in the laboratory.

(f) The condition of unsatisfactory specimens and packages when received (e.g., broken, leaked, hemolyzed, or turbid).

(g) The type of test performed.

(h) The result of the laboratory test and the date the test was completed.

§ 74.54 Laboratory report and record.

(a) The laboratory report shall be sent promptly to the physician or other person who requested the test and a suitable record of each report shall be preserved by the laboratory for not less than 2 years. The name of the laboratory actually performing the examination shall be indicated in the report to the person submitting the specimen.

(b) Tissue pathology and cytology reports shall utilize an established nomenclature.

(c) Reports of quantitative analyses shall include the units of concentration or activity and, where requested or indicated, the usual range of values for good health.

(d) A list of analytical methods employed by the laboratory and documentation of usual range of values for good health shall be made available to the person or laboratory submitting the specimen.

§ 74.55 Equipment and facilities.

The laboratory equipment maintenance program shall assure satisfactory operation of all equipment. Space, facilities, and equipment shall be adequate to properly perform the services offered by the laboratory. Workbench space shall be ample for the type and volume of work being done, and well lighted to facilitate accuracy and precision. There shall be freedom from unnecessary chemical, radiological, biological, and other hazards which may contaminate or otherwise adversely affect examination of specimens and, where applicable, provision shall be made for sterilization of contaminated material.

§ 74.56 Inspection.

The Secretary may conduct an inspection of every licensed laboratory at least annually and may conduct other inspections from time to time. Inspections shall be made at any time during the performance of procedures and services and may include observation of complete examinations of specimens by personnel and methods ordinarily and routinely employed by the laboratory, examination of personnel files, procedural manuals, and records of tests including quality control and calibration. Inspections may be made with or without notice.

§ 74.57 Change in ownership.

The Director shall be notified of any change in the ownership of a licensed laboratory, other than a transfer of stock, within 10 days of any such change.

§ 74.58 Change in director or supervisor.

Changes in directors and in supervisors for any reason shall be reported to the Director within 30 days of the effective date of change.

Subpart H—Revocation, Suspension, and Limitation of Licenses and Letters of Exemption; Notice

§ 74.60 Revocation, suspension, and limitation of licenses and letters of exemption.

A laboratory license or letter of exemption may be revoked, suspended, or limited, whenever the Secretary, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory as provided herein finds, in the case of a license, that such owner, or operator, or any employee of the laboratory has committed any of the actions specified in section 353(e) of the Act, or in the case of a letter of exemption, that the laboratory is no longer eligible for such letter of exemption.

§ 74.61 Contents of notice.

(a) *General.* A notice issued pursuant to § 74.60 shall contain a statement of the proposed action and of the grounds upon which the action is proposed to be taken.

(b) *Suspension.* Where it is proposed to suspend a license or letter of exemption, (1) the period of such proposed suspension or the action which will be required to end the suspension shall be stated in the notice, and (2) the notice shall provide that if the appropriate remedial action is not taken within the period of suspension prescribed, the license or letter will be revoked.

(c) *Limitation.* Where it is proposed to limit a license or letter of exemption, the procedures or categories of procedures with respect to which the license or letter will no longer be applicable shall be stated in the notice.

Subpart I—Hearings [Reserved]

SUBCHAPTER G—OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND RELATED ACTIVITIES

PART 80—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subparts A-C [Reserved]

Subpart D—Tuition Fees for Direct Training

Sec.
80.41 Applicability.
80.42 Definitions.
80.43 Tuition fees.
80.44 Schedule of fees.
80.45 Procedure for payment.
80.46 Refunds.

AUTHORITY: Sec. 501, 65 Stat. 290; 31 U.S.C. 483a.

SOURCE: 38 FR 16645, June 25, 1973, unless otherwise noted.

Subparts A–C [Reserved]

Subpart D—Tuition Fees for Direct Training

§ 80.41 Applicability.

The provisions of this subpart set forth the policies of the National Institute for Occupational Safety and Health with respect to its charging fees for direct training in occupational safety or health.

§ 80.42 Definitions.

Any term not defined herein shall have the same meaning as given it in the act. As used in this subpart:

(a) "Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

(b) "Direct training" means all technical training courses conducted directly by NIOSH for personnel of State and local governmental agencies, other Federal agencies, private industries, universities, and other non-NIOSH agencies and organizations.

(c) "NIOSH" or "Institute" means the National Institute for Occupational Safety and Health.

(d) "Registration Office" means the Direct Training Registration Office, NIOSH, 1014 Broadway, Cincinnati, Ohio 45202.

§ 80.43 Tuition fees.

In accordance with the provisions of the subpart, the National Institute for Occupational Safety and Health will charge fees for all students attending NIOSH direct training courses which commence on or after July 1, 1973.

§ 80.44 Schedule of fees.

(a) Tuition fees will be computed on the basis of the cost to the Government for the Institute's participation in the course, as determined by the Director of the Institute.

(b) Total tuition charges for each course will be set forth in the course announcement.

§ 80.45 Procedure for payment.

(a) Applications for direct training courses shall be completed and submitted to the registration office in accordance with the instructions issued by that office.

(b) Federal agency personnel shall, upon notification of their acceptance, submit a letter identifying the agency and office to be billed, the agency order number, and any code numbers or other information necessary for billing purposes.

(c) All other applicants shall, upon notification of their acceptance by NIOSH, submit a check payable to the National Institute for Occupational Safety and Health in the amount indicated by the course announcement prior to the commencement of the training course.

§ 80.46 Refunds.

An applicant may withdraw his application and receive full reimbursement of the fee provided that written notification to the registration office is mailed no later than 10 days before the commencement of the course for which registration has been submitted.

PART 85—REQUESTS FOR HEALTH HAZARD EVALUATIONS

Sec.
85.1 Applicability.
85.2 Definitions.
85.3 Procedures for requesting health hazard evaluations.
85.3-1 Contents of a request for health hazard evaluations.
85.4 Acting on requests.
85.5 Authority for investigations.
85.6 Advance notice of visits.
85.7 Conduct of investigations.
85.8 Provision of suitable space for employee interviews and examinations; identification of employees.
85.9 Representatives of employers and employees; employee requests.
85.10 Imminent dangers.
85.11 Notification of determination to employers, affected employees, and Department of Labor.
85.12 Subsequent requests for health hazard evaluations.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 37 FR 23640, Nov. 7, 1972, unless otherwise noted.

§ 85.1 Applicability.

This Part 85 applies to health hazard evaluations requested by any employer or authorized representative of employees under section 20(a)(6) of the Occupational Safety and Health Act of 1970 or section 501(a)(11) of the Federal Mine Safety and Health Act of 1977. This part is not intended to preclude the use of other channels of communication with the National Institute for Occupational Safety and Health to obtain information and technical assistance concerning toxic substances or physical agents.

[45 FR 2652, Jan. 14, 1980]

§ 85.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the respective Acts. As used in this part:

"OSH Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651, et seq.).

"FMSH Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, et seq.).

"Authorized representative of employees" means any person or organization meeting the conditions specified in § 85.3-1(e) (1), (2), or (3).

"Employee" has the same meaning as stated in the OSH Act and for the purposes of this part includes "miner" as defined in the FMSH Act.

"Employer" has the same meaning as stated in the OSH Act and for the purposes of this part includes "Operator" as defined in the FMSH Act.

"Health hazard evaluation" means the investigation and the determination of potentially toxic or hazardous effects of: (a) any substance normally used or found in any place of employment to which the OSH Act is applicable, or (b) any substance or physical agent normally used or found in any place of employment to which the FMSH Act is applicable.

"Investigation" means a physical inspection of the place of employment under section 8 of the OSH Act or section 103 of the FMSH Act and includes inspection, sampling, observations, review of pertinent records, and other measurements reasonably necessary to determine whether any substance or physical agent found in the place of employment has potentially toxic or hazardous effects in the concentrations or levels used or found.

"NIOSH" means the National Institute for Occupational Safety and Health, Center for Disease Control, Public Health Service, Department of Health and Human Services.

"NIOSH officer" means a NIOSH employee who has been authorized by the Director, NIOSH, to conduct investigations according to this part.

"Physical agent" means any condition produced by the environment and/or work processes that can result in hazardous effects as defined in this section. Examples of physical agents are noise, temperature, illumination, vibration, radiation, and pressure.

"Place of employment" means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace, or environment where work is performed by any employee of an employer.

"Substance" means any chemical or biological agent or dust which has the potential to produce toxic effects.

"Toxic effects" or "hazardous effects" are those effects which result in short- or long-term disease, bodily injury, affect health adversely, or endanger human life.

[45 FR 2652, Jan. 14, 1980]

§ 85.3 Procedures for requesting health hazard evaluations.

(a) Requests for health hazard evaluations should be addressed to the National Institute for Occupational Safety and Health as follows:

(1) *Requests from general industry.* Hazard Evaluations and Technical Assistance Branch, Division of Surveillance, Hazard Evaluations, and Field Studies, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.

(2) *Requests from mining industry.* Environmental Investigations Branch, Division of Respiratory Disease Studies, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505.

(b) Requests for health hazard evaluations shall be submitted in writing and signed by either: (1) The employer in whose place of employment the substance or physical agent is normally found, or (2) an authorized representative of employees (see § 85.3-1(e)) in the place of employment where the substance or physical agent is normally found.

[45 FR 2653, Jan. 14, 1980]

§ 85.3-1 Contents of a request for health hazard evaluation.

Each request for health hazard evaluation shall contain:

(a) The requester's name, address, and telephone number, if any.

(b) The name and address of the place of employment where the substance or physical agent is normally found.

(c) The specific process or type of work which is the source of the substance or physical agent, or in which the substance or physical agent is used.

(d) Details of the conditions or circumstances which prompted the request.

(e) A statement, if the requester is not the employer, that the requester is:

(1) An authorized representative or an officer of the organization representing the employees for purposes of collective bargaining; or

(2) An employee of the employer and is authorized by two or more employees employed in the same place of employment to represent them for purposes of these Acts (each such authorization shall be in writing and a copy submitted with the request for health hazard evaluation); or

(3) One of three or less employees employed in the place of employment where the substance or physical agent is normally found.

(f) A statement indicating whether or not the name(s) of the requester or those persons who have authorized the requester to represent them may be revealed to the employer by NIOSH.

(g) The following supplementary information if known to the requester:

(1) Identity of each substance or physical agent involved;

(2) The trade name, chemical name, and manufacturer of each substance involved;

(3) Whether the substance or its container or the source of the physical agent has a warning label; and

(4) The physical form of the substance or physical agent, number of people exposed, length of exposure (hours per day), and occupations of exposed employees.

NOTE: NIOSH has developed two forms entitled "Request for Health Hazard Evaluation" and "Request for Mining Health Hazard Evaluation" to assist persons in requesting evaluations. The forms are available upon request from the offices listed in § 85.3(a) (1) and (2) or from the Regional Consultant for Occupational Safety and Health in any Regional Office of the Department of Health and Human Services.

[45 FR 2653, Jan. 14, 1980]

§ 85.4 Acting on requests.

(a) Upon receipt of a request for health hazard evaluation submitted under this part, NIOSH will determine whether or not there is reasonable cause to justify conducting an investigation.

(b) If NIOSH determines that an investigation is justified, a NIOSH officer will inspect the place of employment, collect samples where appropriate, and perform tests necessary to the conduct of a health hazard evaluation, including medical examinations of employees.

(c) If NIOSH determines that an investigation is not justified, the requester will be notified in writing of the decision.

[45 FR 2653, Jan. 14, 1980]

§ 85.5 Authority for investigations.

(a) NIOSH officers who have been issued official NIOSH credentials (Form No. CDC/NIOSH 2.93) are authorized by the Director, NIOSH, under sections 20(a) (6) and 8 of the OSH Act and sections 501(a)(11) and 103 of the FMSH Act: To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements, and functional tests of employees within the place of employment as may be directly related to the specific health hazard evaluation being conducted. Investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigation, the NIOSH officers may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, and duplicate records required by the Acts and regulations and any other related records.

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH officers who have obtained the proper security clearance and authorization.

[45 FR 2653, Jan. 14, 1980]

§ 85.6 Advance notice of visits.

(a) Advance notice of visits to the place of employment may be given to expedite a thorough and effective investigation. Advance notice will not be given when, in the judgment of the NIOSH officer, giving such notice would adversely affect the validity and effectiveness of the investigation.

(b) Where a request in accordance with this part has been made by an authorized representative of employees, advance notice in accordance with paragraph (a) of this section will be given by NIOSH to the requester, the representative of the employees for purposes of collective bargaining if such representative is other than the requester, and to the employer.

(c) Where a request in accordance with this part has been made by any employer, advance notice will be given by NIOSH to the employer. Upon the request of the employer, NIOSH will inform the authorized representative of employees of the visit: *Provided,* The employer furnishes NIOSH in writing with the identity of such representative and with such information as is necessary to enable NIOSH promptly to inform such representative of the visit.

§ 85.7 Conduct of investigations.

(a) Prior to beginning an investigation, NIOSH officers shall present their credentials to the owner, operator, or agent in charge at the place of employment, explain the nature, purpose, and scope of the investigation and the records specified in § 85.5 which they wish to review. Where the investigation is the result of a request submitted by an authorized representative of employees, a copy of the request shall be provided to the employer, except where the requester or any person authorizing the requester pursuant to § 85.3-1(e)(2) has indicated that NIOSH not reveal his name to the employer, in which case a summary of the basis for the request shall be provided to the employer.

(b) At the commencement of an investigation, the employer should precisely identify information which can be obtained in the workplace or workplaces to be inspected as trade secrets.

If the NIOSH officer has no clear reason to question such identification, such information shall not be disclosed except in accordance with the provisions of section 20(a)(6) and section 15 of the OSH Act or section 501(a)(11) of the FMSH Act. However, if NIOSH at any time questions such identification by an employer, not less than 15 days' notice to an employer shall be given of the intention to remove the trade secret designation from such information. The employer may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, shall notify the employer in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(c) NIOSH officers are authorized to collect environmental samples and samples of substances, or measurements of physical agents to take or obtain photographs related to the purpose of the investigation, employ other reasonable investigative techniques, including medical examinations of employees with the consent of such employees, and to question privately any employer, owner, operator, agent, or employee. The employer shall have the opportunity to review photographs taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(d) NIOSH officers shall comply with all safety and health rules and practices at the place of employment being investigated, and they shall provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer.

(e) The conduct of investigations shall be such as to preclude unreasonable disruption of the operations of the employer's establishment.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.8 Provision of suitable space for employee interviews and examinations; identification of employees.

An employer shall, in request of the NIOSH officer, provide suitable space, if such space is reasonably available, to NIOSH to conduct private interviews with, and examinations of, employees. NIOSH officers shall consult with the employer as to the time and place of the medical examination and shall schedule such examinations so as to avoid undue disruption of the operations of the employer's establishment. NIOSH shall conduct, and assume the medical costs of, examinations conducted under this part.

§ 85.9 Representatives of employers and employees; employee requests.

(a) NIOSH officers shall be in charge of investigations. Where the request for a health hazard evaluation has been made by an authorized representative of employees, a representative of the employer and a representative authorized by his employees who is an employee of the employer shall be given an opportunity to accompany the NIOSH officer during the initial physical inspection of any workplace for the purpose of aiding the investigation by identifying the suspected hazard. The NIOSH officer may permit additional employer representatives and such additional representatives authorized by employees to accompany him where he determines that such additional representatives will further aid the investigation. However, if in the judgment of the NIOSH officer, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough investigation of the workplace, such third party may accompany the NIOSH officer during the inspection: *Provided, however,* That access by such persons to areas described in paragraph (d) of this section shall be in accordance with the requirements of such provision, and access to areas described in paragraph (e) of this section shall be with the consent of the employer. A different employer and employee representative may accompany the officer during each different phase of an inspection if this will not interfere with the conduct of the investigation.

(b) NIOSH officers are authorized to resolve all disputes as to who is the representative authorized by the employer and employees for the purpose of this section. If there is no authorized representative of employees, or if the NIOSH officer is unable to determine with reasonable certainty who is such representative, he shall consult with a reasonable number of employees concerning matters directly related to the health hazard evaluation.

(c) NIOSH officers are authorized to deny the right of accompaniment under this section to any person whose conduct interferes with a fair and orderly physical inspection.

(d) With regard to information classified by an agency of the U.S. Government in the interest of national security, only persons authorized to have access to such information may accompany an officer in areas containing such information.

(e) Upon request of an employer, any representative authorized under this § 85.9 by employees in any area containing trade secrets shall be an employee in that area or an employee authorized by the employer to enter that area.

§ 85.10 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH officer believes that there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer and those employees who appear to be in immediate danger of such allegation and will inform appropriate representatives of the Department of Labor or the State agency designated under section 18(b) of the OSH Act.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.11 Notification of determination to employers, affected employees and Department of Labor.

(a) Upon conclusion of an investigation, NIOSH will make a determination concerning the potentially toxic or hazardous effects of each substance or physical agent investigated as a result of the request for health hazard evaluation. At a minimum, the determination will: (1) Identify each substance or physical agent involved and describe, where appropriate, the concentrations or levels of the substance or physical agent found in the place of employment and the conditions of use, and (2) state whether each substance or physical agent has potentially toxic or hazardous effects in the concentrations or levels found, as well as the basis for the judgments.

(b) Copies of the determination will be mailed to the employer and to the authorized representatives of employees.

(c) Except as hereinafter provided, the employer shall post a copy of the determination for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. The employer will not be required to post the determination if the employer requests that copies of the determination be mailed to affected employees and furnishes NIOSH with a list of the names and mailing addresses of the employees employed in the workplace(s) designated by the NIOSH Officer. In the latter event, NIOSH will mail such copies to affected employees at the mailing addresses provided by the employer.

(d) For purposes of this section, the term "affected employees" means those employees determined by NIOSH to be exposed to the substance(s) or physical agent(s) which is the subject of the health hazard evaluation.

(e) Copies of determinations made under the OSH Act will be forwarded to the Department of Labor and the appropriate State agency designated under section 18(b) of the OSH Act. Copies of determinations made under the FMSH Act will be forwarded to the Mine Safety and Health Administration of the Department of Labor; the Bureau of Mines, Department of the Interior; and the State agency which, in the judgment of NIOSH, would benefit the most from the information. If NIOSH determines that any substance or physical agent has potentially toxic or hazardous effects at the concentrations or levels at which it is used or found in a place of employment, and the substance or physical agent is not covered by a safety or health standard established under section 6 of the OSH Act or section 101 of the FMSH Act, NIOSH will immediately submit the determination to the Secretary of Labor, together with all pertinent criteria.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.12 Subsequent requests for health hazard evaluations.

If a request is received for a health hazard evaluation in a place of employment in which an evaluation under this part was made previously, NIOSH may make another investigation if, as a result of the passage of time or additional information, another investigation would be consistent with the purposes of the Acts.

[45 FR 2654, Jan. 14, 1980]

PART 85a—OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT

Sec.
85a.1 Applicability.
85a.2 Definitions.
85a.3 Authority for investigations of places of employment.
85a.4 Procedures for initiating investigations of places of employment.
85a.5 Conduct of investigations of places of employment.
85a.6 Provision of suitable space for employee interviews and examinations.
85a.7 Imminent dangers.
85a.8 Reporting of results of investigations of places of employment.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 41 FR 45002, Oct. 14, 1976, unless otherwise noted.

§ 85a.1 Applicability.

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.

(b) The provisions of this part do not apply to those activities covered by Part 85 of this chapter.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

(a) "OSH Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.) and "FMSH Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.).

(b) "Assistant Regional Director" means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

(c) "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation any time without prejudice to the subject.

(d) "Investigation" means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

(e) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

(f) "NIOSH" means the National Institute for Occupational Safety and Health of the Center for Disease Control, Public Health Service, Department of Health and Human Services.

(g) "NIOSH authorized representative" means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

(h) "NIOSH Regional Office" means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in § 5.31 of Title 45, Code of Federal Regulations.

(i) "Place of employment" means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

(j) "MSHA District Office" means any one of the Mine Safety and Health Administration's District Offices.

(k) "BOM" means the Bureau of Mines, Department of the Interior.

(l) "Employee" has the same meaning as stated in the OSH Act and for the purposes of this part includes "miner" as defined in the FMSH Act.

(m) "Employer" has the same meaning as stated in the OSH Act and for the purposes of this part includes "operator" as defined in the FMSH ACT.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.3 Authority for investigations of places of employment.

(a) NIOSH authorized representatives who have been issued official NIOSH credentials are authorized by the Director, NIOSH, under sections 20 and 8 of the OSH Act, sections 501 and 103 of the FMSH Act, and this part. To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements and functional tests of employees within the place of employment as may be directly related to the specific investigation being conducted. Such investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigations, such NIOSH authorized representatives may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, or duplicate employment records, medical records, records required by the Act and regulations, and other related records. In those instances where systems of records subject to review, abstraction or duplication are of a confidential nature, such as medical records, and are abstracted or duplicated, NIOSH will maintain such systems in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR Part 5b).

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH authorized representatives who have obtained the appropriate security clearance and authorization.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.4 Procedures for initiating investigations of places of employment.

(a) Except as otherwise provided in paragraph (b) of this section, NIOSH authorized representatives will contact an official representative of the place of employment prior to any site visits and will provide the details of why an investigation of the place of employment is being conducted. Prior to the initiation of a site visit of a place of employment, representatives of the following organizations will be advised of the site visit and the reason for its conduct:

(1) The appropriate State agency designated under section 18(b) of the OSH Act, or if no State agency has been designated under the OSH Act and in the case of the FMSH Act, the State agency which, in the judgment of NIOSH, would benefit the most from the investigation's findings;

(2) If there is a local union at the place of employment, the local president, business manager or other appropriate individual;

(3) The appropriate Assistant Regional Director, when investigations are conducted under the OSH Act;

(4) The appropriate MSHA District Office; the Director, BOM, and the Assistant Director for Mining, BOM, when investigations are conducted under the FMSH Act.

(b) Advance notice of site visits will not be given to the place of employment or local union at the place of employment when, in the judgment of the NIOSH authorized representatives, giving such notice would adversely affect the validity and effectiveness of an investigation. Those individuals and organizations specified in § 85a.4(a)(1), (a)(3) and (a)(4) will be notified prior to the initiation of such a site visit. After the site visit has been initiated, and, as soon as possible thereafter, the NIOSH authorized representatives will contact those individuals specified in § 85a.4(a)(2) concerning the nature and details of the site visit.

(c) In those instances where site visits are not necessary to the conduct of an investigation, the NIOSH authorized representatives will contact an official representative of the place of employment either verbally or through a written communication and provide the details of why an investigation of the place of employment is being conducted. If appropriate, the NIOSH authorized representatives will contact those individuals stipulated in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section about the nature and details of the investigation.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.5 Conduct of investigations of places of employment.

(a)(1) Prior to beginning a site visit, NIOSH authorized representatives will present their credentials to the employer, owner, operator or agent in charge at the place of employment, explain the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(2) In those instances where site visits are not necessary to the conduct of an investigation and the initial contact is made verbally, NIOSH authorized representatives will, at the request of the employer, owner, operator or agent in charge at the place of employment, provide a written explanation of the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(b)(1) At the commencement of an investigation, the employer, owner, operator or agent in charge at the place of employment shall precisely identify that information which is trade secret and might be seen or obtained by the NIOSH authorized representatives during the investigation. If the NIOSH authorized representatives have no clear reason to question such identification, such information will not be disclosed by NIOSH in accordance with the provisions of section 15 of the OSH Act. Generally, NIOSH will not question trade secret designations; however, if NIOSH at any time does question such identification, not less than 15 days' notice to the employer, owner, operator or agent will be given of the intention to remove the trade secret designation from such information. The employer, owner, operator or agent may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, will notify the employer, owner, operator or agent in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contact agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act, the employer, owner, operator or agent in charge at the place of employment may, after advising the NIOSH contractor or consultant in writing, elect to withhold information deemed to be a trade secret from such a NIOSH authorized representative or prohibit entry into the area of the place of employment where such entry will reveal trade secrets. In those instances, where the subject information is needed or access to the area of the place of employment is necessary, in the judgment of NIOSH, to fulfill the goals of the investigation, NIOSH regular employees will then obtain the information or enter the subject area of the place of employment.

(c)(1) NIOSH authorized representatives will be in charge of site visits conducted pursuant to this part.

(2) Where there is a request by the representative of the State agency and/or employees, who were notified pursuant to § 85a.4(a)(1) or § 85a.4(a)(2) to accompany the NIOSH authorized representatives during the site visit of the place of employment, the NIOSH authorized representatives will allow this request if they determine that this will aid the investigation; or where, in the judgment of the NIOSH authorized representatives, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough site visit, they may permit such third party to accompany them during the site visit: *Provided, however,* That access by such person(s) to areas described in § 85a.5(c)(4) shall be in accordance with the requirements of such provision and access to areas containing trade secrets shall be with the consent of the employer, owner, operator or agent in charge at the place of employment.

(3) NIOSH authorized representatives are authorized to deny the right of accompaniment under this paragraph to any person whose conduct in their judgment interferes with a fair and orderly site visit. In all instances, a representative of the employer shall be permitted to accompany the NIOSH authorized representatives during the site visit of the place of employment.

(4) With regard to information classified by an agency of the United States Government in the interest of national security, only persons authorized to have access to such information may accompany NIOSH authorized representatives in areas containing such information.

(d)(1) NIOSH authorized representatives are authorized: To collect environmental samples and samples of substances; to measure environmental conditions and employee exposures; to take or obtain photographs, motion pictures or video tapes related to the purpose of the investigation; to employ other reasonable investigative techniques, including medical examinations, anthropometric measurements and standardized and experimental functional tests of employees with the informed consent of such employees; to review, abstract and duplicate such personnel records as are pertinent to mortality, morbidity, injury, safety and other similar studies; and to question and interview privately any employer, owner, operator, agent or employee from the place of employment. The employer, owner, operator, or agent shall have the opportunity to review photographs, motion pictures and video tapes taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(2) Prior to the conduct of medical examinations, anthropometric measurements or functional tests of any employees, the NIOSH authorized representatives will obtain approval of the procedures to be utilized from the NIOSH Human Subjects Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

(e) NIOSH authorized representatives will comply with all safety and health rules and practices at the place of employment and all NIOSH, Occupational Safety and Health Administration, and Mine Safety and Health Administration regulations and policies during a site visit and will provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer, owner, operator or agent in charge at the place of employment.

(f) The conduct of site visits will be such as to preclude unreasonable disruption of the operations of the place of employment.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.6 Provision of suitable space for employee interviews and examinations.

An employer, owner, operator or agent in charge at the place of employment shall, on request of the NIOSH authorized representatives, provide suitable space at the place of employment, if such space is reasonably available, to NIOSH to conduct private interviews with, and medical examinations, anthropometric measurements and functional tests of employees. NIOSH authorized representatives will consult with the employer, owner, operator or agent as to the time and place of the private interviews, medical examination, anthropometric measurements and functional tests and will schedule same so as to avoid undue disruption of work at the place of employment. NIOSH will conduct the medical interviews, measurements, examinations and tests specified under this part at its own expense.

§ 85a.7 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH authorized representatives believe there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer, owner, operator or agent in charge at the place of employment and those employees who appear to be in immediate danger of such allegation and will inform the agencies identified in § 85a.4(a)(1), (a)(3), and (a)(4).

[41 FR 45002, Oct. 16, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.8 Reporting of results of investigations of places of employment.

(a)(1) Specific reports of investigations of each place of employment under this part, with identification of the place of employment, will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, with copies to the appropriate officials and Agencies notified pursuant to § 85a.4(a). Prior to release of such reports, a preliminary report will be sent by NIOSH to the employer, owner, operator or agent for review for trade secret information and technical inaccuracies that may inadvertently be presented in the report. If requested in writing, the data used to compile the reports will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, except that data will not be released in a form that is individually identifiable.

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Regional Consultant for Occupational Safety and Health in the appropriate NIOSH Regional Office.

(3) In certain instances, specific reports of investigations of each place of employment will not be prepared. In such instances, a closing conference at the place of employment will be conducted by the NIOSH authorized representatives and those individuals participating in the site visit to discuss the findings of the site visit and appropriate recommendations.

(b)(1) Any specific findings of individual employee medical examinations, anthropometric measurements and functional tests will be released by NIOSH authorized representatives to the company physician, private physician, or other person only pursuant to the written authorization of the employee; otherwise, the specific findings and other personal records concerning individuals will be maintained in accordance with 45 CFR Part 5b and section 3 of the Privacy Act of 1974 (5 U.S.C. 552a). Notice of all NIOSH systems of records as defined in 45 CFR

5b.1(n) as a result of the investigations of places of employment pursuant to this part will be published in the FEDERAL REGISTER under Notices of Systems of Records for the Department of Health and Human Services.

(2) In cases where an employee shows positive significant medical findings, the employee and the physician(s) designated by the employee under § 85a.8(b)(1) will be immediately notified by NIOSH.

(3) A summary of the findings of the examinations for each employee will be sent by NIOSH to the individual.

(c) The findings of a total investigation generally will be disseminated as part of NIOSH criteria documents, NIOSH technical reports, NIOSH information packets, scientific journals, presentations at technical meetings, or in other similar manners. These findings of a total investigation will be presented in a manner which does not identify any specific place of employment; however, it should be noted that the specific reports of investigations of each place of employment under this part are subject to mandatory disclosure, upon request, under the provisions of the Freedom of Information Act (5 U.S.C. 552).

PART 86—GRANTS FOR EDUCATION PROGRAMS IN OCCUPATIONAL SAFETY AND HEALTH

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AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g), sec. 21(a), 84 Stat. 1612; 29 U.S.C. 670(a).

SOURCE: 40 FR 29076, July 10, 1975, unless otherwise noted.

Subpart A—General

§ 86.1 Applicability.

The regulations of this part are applicable to the award of training grants and direct traineeships pursuant to section 21(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 670(a)(1)) to assist in providing an adequate supply of qualified personnel to carry out the purposes of the Act.

§ 86.2 Definitions.

Any term not defined herein shall have the same meaning as given it in the Act. As used in this part:

(a) "Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

(b) "Nonprofit agency or institution" means an agency, corporation, or association no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) "State" means a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands.

(e) "Training" means job-specific skill development, the purpose of which is to provide qualified personnel to carry out the purposes of the Act.

§ 86.3 Inventions and discoveries.

Any grant award pursuant to § 86.14 or § 86.33 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 86.4 Publications and copyrights.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose, of such materials and to authorize others to do so.

§ 86.5 Grant appeals procedure.

The informal Public Health Service procedure for resolution of post-award grant disputes set forth in Subpart D of Part 50 of this title and the Department post-award grant appeals procedure in 45 CFR Part 16 are applicable to any award made pursuant to this part.

Subpart B—Occupational Safety and Health Training Grants

§ 86.10 Nature and purpose of training grants.

(a) *Long-term training project grant.* A long-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project," that are undertaken to establish, strengthen, or expand graduate, undergraduate, or special training, of persons in the field of occupational safety and health. Such grants may be used to support training in, for example, occupational medicine, industrial hygiene, industrial nursing and occupational safety engineering and the training of technicians and paraprofessionals in such areas.

(b) *Short-term training project grant.* A short-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project" that are undertaken to provide intensive training programs of less than 1 year for any one or a combination of the following purposes:

(1) To provide specialized instruction for occupational safety and health professional or career personnel which will increase their competence in an area in their respective fields.

(2) To prepare or expand the capabilities of occupational safety and health professional or career personnel for leadership roles as administrators or supervisors, and

(3) To prepare or expand the teaching capabilities of occupational safety and health professionals and career personnel.

(c) *Educational Resource Center Grant.* An educational resource center grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project," that are undertaken to provide for the combination of long-term and short-term training activities as described in § 86.13 (c).

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

§ 86.11 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit educational or training agency or institution located in a State is eligible to apply for a grant under this subpart.

(b) *Projects eligible for long-term or short-term training grants or educational resource center grants.* Any project found by the Secretary to be a long-term training project within the meaning of § 86.10(a) or a short-term training project within the meaning of § 86.10(b) or an educational resource center grant project within the meaning of § 86.10(c) shall be eligible for a grant award. However, no applicant is eligible for assistance for a separate training project grant in any project period in which it receives an educational resource center grant. Nothing in the section shall prevent an existing training grant from being incorporated into an educational resource center grant award.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

§ 86.12 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project in accordance with the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

§ 86.13 Project requirements.

(a) An approvable application for a long-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a method for development of the training curriculum and any attendant training materials and resources;

(2) Provision of a method for implementation of the needed training;

(3) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program; and

(4) Provision of a method by which trainees will be selected.

(b) In addition to the requirements set forth in paragraph (a) of this section, an approvable application for a short-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a methodology to assess the particular skills, or knowledge that prospective trainees need to develop;

(2) Provision of at least 18 hours of formal instruction for a period of not less than 2½ days and not more than 1 academic year; and

(3) Assurances that no portion of the Federal funds will be used for (i) inservice training courses designed only for employees of a single agency, institution, or organization; (ii) correspondence courses; (iii) regular courses usually given for academic credit; or (iv) training the grantee's financial officers, program director, or the official who executed the application.

(c) In addition to the requirements set forth in paragraphs (a), (b)(1), and (b)(3) (ii), (iii) and (iv) of this section, an approvable application for an educational resource center grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission:

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[1] Applications and instructions may be obtained from the Office of Extramural Activities, National Institute for Occupational Safety and Health, U.S. Post Office & Courthouse, Cincinnati, Ohio 45202.

(1) A description, supported by appropriate documents, of cooperative arrangements to conduct an educational resource center among a medical school (with an established program in preventive or occupational medicine), a school of nursing, a school of public health or its equivalent, and a school of engineering or its equivalent. Other schools or departments with relevant disciplines and resources—e.g., toxicology, biostatistics, environmental health, law, business administration, education—may be represented and contribute as appropriate to the conduct of the total program.

(2) The identification of an educational resource center Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational safety and health training who shall oversee the general operation of the educational resource center program and shall, to the extent possible, directly participate in training activities.

(3) A description of the full-time professional staff representing various disciplines and qualifications relevant to occupational safety and health and capable of planning, establishing, and carrying out or administering training projects undertaken by the educational resource center.

(4) A description of the training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

(5) A description of its program for conducting education and training of occupational health physicians, occupational health nurses, industrial hygienists/engineers and safety personnel. There shall be full-time students in each of these core disciplines, with a goal of a minimum total of 30 full-time students. Training may also be conducted in other occupational safety and health career categories, e.g., industrial toxicology, biostatistics, epidemiology, and ergonomics. Training programs shall include appropriate field experience including experience with public health and safety agencies and labor-management health and safety activities.

(6) A specific plan for making an impact on the curriculum taught by relevant medical specialties, including radiology, orthopedics, dermatology, internal medicine, neurology, perinatal medicine, and pathology.

(7) A description of its program to assist other institutions or agencies located within the applicant's region including schools of medicine, nursing and engineering, among others, by providing curriculum materials and consultation for curriculum/course development in occupational safety and health, and by providing training opportunities for faculty members.

(8) A specific plan for preparing, distributing, and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel of labor-management health and safety committees, in the geographical region in which the educational resource center is located. The content and orientation of the curriculum/courses shall take into consideration and address problems relevant to the geographic region served. The goal shall be that the training be made available each year to a minimum of 200-250 trainees representing all of the above categories of personnel with priority given to providing occupational safety and health training to physicians in family practice, as well as in industrial practice, and industrial nurses. These courses shall be structured so that educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational safety and health personnel working in the workplace. Further, the educational resource center shall have a specific plan and demonstrated capability for implementing such training directly and through other institutions or agencies in the region including cooperative efforts with labor unions and industry trade associations where appropriate.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

§ 86.14 Evaluation and grant award.

Within the limits of funds available for such purpose the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 21(a)(1) of the Act, taking into account:

(a) In the case of long-term training grants:

(1) The need for training in the area or areas of study outlined in the application;

(2) The degree to which the proposal represents a strengthening or expansion of the applicant's program in such areas;

(3) The record of the applicant's effectiveness in training in these or related areas as indicated, among other things, by the placement of its graduates;

(4) The competence of the project staff in relation to the service to be provided;

(5) The reasonableness of the budget in relation to the proposed project;

(6) The applicant's resources, including equipment, facilities, and funds, available for the project;

(7) The current and potential availability of students in the area of study to be offered and their prospective employability as a result of the proposed training;

(8) The extent to which the applicant expects to absorb faculty positions initiated as a result of the grant; and

(9) The degree to which the project adequately provides for the requirements set forth in § 86.13(a).

(b) In the case of short-term training:

(1) The relationship of the contents of the course to the current and emergency training needs to carry out the purposes of the Act;

(2) The qualifications of the instructional staff;

(3) The speed with which the training can be put to use by the persons proposed to be trained;

(4) The reasonableness of the budget in relation to the proposed project;

(5) The success of previous offerings of this course, or related courses;

(6) Evidence of ability to recruit trainees and the estimated number to be enrolled during each course offering; and

(7) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(b).

(c) In the case of educational resource center grants:

(1) The criteria set forth in paragraphs (a) and (b) of this section.

(2) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(c).

(d) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (1) on the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage, not to exceed 8 percent, of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(e) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(f) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52402, Sept. 30, 1977]

§ 86.15 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 86.16 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with section 21(a) of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Prior written approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities, which in the case of short term training grants, includes any change in the course dates or training sites.

(c) Grant funds are available for trainee stipends and for tuition, including fees and instructional materials, for travel costs related to training allowances. Stipends and allowances may not be increased or be paid beyond the term of the stipend on account of vacation an individual might have been entitled to but did not take.

(d) Stipends may only be paid to a trainee who is a citizen of the United States, an alien lawfully admitted to the United States for permanent residence, or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(e) In the case of short term training grants, stipends may not be paid to persons receiving lecture fees, salary, travel expenses, or payment in any form as members of the course instructional staff.

(f) Grant funds used for alterations and renovations shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, as amended, and with the applicable regulations prescribed pursuant thereto.

§ 86.17 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to, discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this subpart, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of title IX of the Education Amendments of 1972 (86 Stat. 373, 20 U.S.C. 1681 et seq.) and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(c) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 86.18 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political sudivisions of the State. All grantees other than a State, as defined in this section, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section; and

(ii) Any credits for earned interest pursuant to paragraph (b) of this section; and

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 86.19 Human subjects; animal welfare.

No grant award may be made under this subpart unless the applicant has complied with:

(a) 45 CFR Part 46 pertaining to the protection of human subjects; and

(b) Chapter 1-43 of the Department Grants Administration Manual[2] concerning animal welfare.

§ 86.20 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 86.21 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all grantee organizations under this part:

45 CFR PART 74

Subpart and Subject	
A	General.
B	Cash depositories.
C	Bonding and insurance.
D	Retention and custodial requirements for records.
F	Grant-related income.
G	Matching and cost sharing.
K	Grant payment requirements.
L	Budget revision procedures.
M	Grant closeout: Suspension, and termination.
O	Property.
Q	Cost principles.

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[2] The Department Grants Administration Manual is available for inspection at the Public Information Office of the several Department Regional Offices and available for purchase at the Government Printing Office, GPO Document No. 894-523.

Subpart C—Occupational Safety and Health Direct Traineeships

§ 86.30 Nature and purpose of direct traineeships.

A direct traineeship is an award of funds directly from the Federal Government to an individual (herein called the "trainee") for his subsistence and other expenses during a period in which he is acquiring training (a) in the occupational safety and health professions, (b) for research relating to occupational safety and health, or (c) for teaching in occupational safety and health.

§ 86.31 Eligibility: minimum requirements.

In order to be eligible for an award under this subpart an applicant must:

(a) Have been accepted by a public or other nonprofit institution for the purpose of the activity for which the traineeship is sought.

(b) Be a U.S. citizen, an alien lawfully admitted to the United States for permanent residence or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 86.32 Application for direct traineeship.

An application for a direct traineeship under this subpart shall be submitted to the Secretary at such times and in such form and manner as he may prescribe.[1] In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his or her qualifications.

§ 86.33 Human subjects; animal welfare.

Where the application is for training at a non-Federal institution, no award may be made under this subpart unless said institution has complied with:

(a) 45 CFR Part 46 pertaining to the protection of human subjects; and

(b) Chapter 1-43 of the Department Grants Administration Manual[2] concerning animal welfare.

§ 86.34 Evaluation and award of direct traineeships.

Within the limits of funds available for such purpose and subject to the regulations of this part, the Secretary may award direct traineeships to those qualified applicants who are in his judgment best able to carry out the purpose of the traineeships taking into consideration the need for training in the area of study specified in the application.

§ 86.35 Payments.

(a) Individuals receiving awards shall be entitled to such stipends and allowances as the Secretary may designate, taking into account such factors as the needs of the program, the cost of living, and the availability of funds.

(Note: These are prescribed in Chapter 3-140 of the Department Grants Administration Manual[2]).

(b) Payments of stipends and allowances will, at the discretion of the Secretary, be made directly to the trainee or to the sponsoring institution for payment directly to the trainee.

§ 86.36 Duration and continuation.

Direct traineeship awards may be made for varying periods not in excess of 2 years. The Secretary may make one or more continuation awards for an additional period if he finds that satisfactory progress is being made toward accomplishment of the purpose of the initial traineeship award. Additional support may be provided on appropriate justification after expiration of the period of support in the previous award.

§ 86.37 Terms and conditions.

All direct traineeship awards shall be subject to the following terms and conditions:

(a) Training must be carried out at an institution found by the Secretary to provide a well-rounded course of instruction in the particular area of training for which the traineeship is awarded.

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[1] Applications and instructions may be obtained from the Office of Extramural Activities, National Institute for Occupational Safety and Health, U.S. Post Office & Courthouse, Cincinnati, OH 45202.

[2] See footnote 2 to § 86.19.

(b) No direct traineeship may be utilized to compensate any trainee for personal services or employment on behalf of the United States or any person.

§ 86.38 Accountability.

Accountability for payments will be subject to such requirements as may be specified by the Secretary.

§ 86.39 Termination of direct traineeship.

(a) The Secretary may terminate a direct traineeship at any time upon request of the trainee.

(b) After reasonable notice to the trainee and an opportunity for the presentation of the trainee's views and relevant evidence, the Secretary may terminate any direct traineeship prior to the date it would otherwise expire upon a determination that the trainee's performance is unsatisfactory, that the trainee is no longer attending the sponsoring institution, or that he or she is unfit or unable to carry out the purpose of the traineeship.

(c) The views and evidence of the trainee shall be presented in writing unless the Secretary determines that an oral presentation is desirable.

PART 87—NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND DEMONSTRATION GRANTS

Sec.

87.1 To which programs does this regulation apply?
87.2 Definitions.
87.3 Who is eligible to apply for a grant under this part?
87.4 For what purposes may grants be awarded?
87.5 What information must be included in the grant application?
87.6 How will grant applications be evaluated and the grants awarded?
87.7 For what period of time will grants be awarded?
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87.9 Which other HHS regulations apply?

AUTHORITY: Sec. 8(g), 84 Stat. 1600 (29 U.S.C. 657(g)), sec. 508, 83 Stat. 803 (30 U.S.C. 957).

SOURCE: 46 FR 58676, Dec. 3, 1981, unless otherwise noted.

§ 87.1 To which programs does this regulation apply?

This regulation applies to research and demonstration project grants under: (a) Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1)) for the support of studies related to occupational safety and health, and (b) section 501 of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951) for the support of health research in mining. These grants are awarded and administered by the National Institute for Occupational Safety and Health, Centers for Disease Control, of the Public Health Service.

§ 87.2 Definitions.

As used in this regulation:

"Demonstration project grant" means an award of funds to an eligible applicant to assist in meeting the cost of conducting a demonstration, either on a pilot or full-scale basis, of the technical or economic feasibility or application of a new or improved procedure, method, technique, or approach that will further the research purposes described in § 87.4.

"Principal investigator" for a research project, or "project director" for a demonstration project, means a single individual who is responsible for the scientific and technical direction of the project.

"Research project grant" means an award of funds to an eligible applicant to assist in meeting the costs of conducting an identified research activity or program, study, or experiment that will further the research purposes described in § 87.4.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

§ 87.3 Who is eligible to apply for a grant under this part?

Any public or private agency or institution is eligible to apply for a grant under this part, except Federal agencies or institutions not specifically authorized by law to receive such a grant.

§ 87.4 For what purposes may grants be awarded?

(a) The Occupational Safety and Health Act authorizes grants for research, experiments, and demonstrations relating to occupational safety and health, including studies of the psychological factors involved. This authority includes projects to develop innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(b) The Federal Mine Safety and Health Act authorizes grants for research projects designed to:

(1) Improve working conditions and practices affecting health in coal or other mines and to prevent occupational diseases originating in the mining industry.

(2) Develop epidemiological information to (i) identify and define positive factors involved in occupational diseases of miners, (ii) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (iii) improve health standards.

(3) Develop techniques for the prevention and control of occupational diseases of miners, including tests for hypersusceptibility and early detection.

(4) Evaluate the effect on bodily impairment and occupational disability of miners afflicted with an occupational disease.

(5) Study the relationship between coal or other mine environments and occupational diseases of miners.

(6) Study matters involving the protection of life and the prevention of diseases in connection with persons who, although not miners, work with or around the products of coal or other mines in areas outside of such mines and under conditions which may adversely affect the health and well-being of such persons.

(7) Develop effective respiratory equipment.

§ 87.5 What information must be included in the grant application?

The application must contain a complete description of the objective of the project and the plan for carrying out the research or demonstration, the name and qualifications of the principal investigator or project director and principal staff members, the total resources and facilities that will be available, and a justification of the amount of grant funds requested.

§ 87.6 How will grant applications be evaluated and the grants awarded?

(a) The Secretary may award grants to those applicants whose approved projects will best promote the purposes of either the Occupational Safety and Health Act or the Federal Mine Safety and Health Act on the basis of an evaluation conducted by experts or consultants engaged for this purpose.

(b) This evaluation will take into account the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research or demonstration involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, the adequacy of the applicant's resources available for the project, the amount of grant funds necessary for completion, and for mining grant applications, the recommendations of the Mine Health Research Advisory Committee.

(c) The Secretary may evaluate and approve two or more concurrent applications, each dealing with one or more specified aspects of the project, and make two or more concurrent grant awards for the project. This may be necessary when a project involves a number of different but related problems, activities, or disciplines which would require evaluation by different groups, or when support for a project could be more effectively administered by separate handling of various aspects of the project.

§ 87.7 For what period of time will grants be awarded?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3-5 years.

(b) Generally, the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 87.8 How may a grantee use grant funds?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, the terms and conditions of the grant award, the applicable cost principles specified in Subpart Q of 45 CFR Part 74, and the regulations of this part.

§ 87.9 Which other HHS regulations apply?

Several other regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50—Subpart D—PHS grant appeals procedure.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 46—Protection of human subjects.
45 CFR Part 74—Administration of grants.
45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations).
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 91[1]—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

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[1] Refer to 45 CFR Part 90 until Part 91 is issued.

SUBCHAPTER H—[RESERVED]

SUBCHAPTER I—MEDICAL CARE QUALITY AND COST CONTAINMENT

PART 100—COST CONTAINMENT AND QUALITY CONTROL

Subpart A—Limitation on Federal Participation for Capital Expenditures

Sec.
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AUTHORITY: Sec. 1122, Social Security Act; 42 U.S.C. 1320a-1.

SOURCE: 38 FR 31381, Nov. 13, 1973, unless otherwise noted.

Subpart A—Limitation on Federal Participation for Capital Expenditures

§ 100.101 Applicability.

The provisions of this subpart are applicable to agreements entered into by the Secretary with the various States pursuant to section 1122 of the Social Security Act (42 U.S.C. Chap. 7), and to determinations made by the Secretary thereunder, for the purpose of assuring that Federal funds appropriated under titles V, XVIII, and XIX of the Social Security Act are not used to support unnecessary capital expenditures made by or on behalf of health care facilities or health maintenance organizations which are reimbursed under any of such titles and that, to the extent possible, reimbursement under such titles shall support planning activities with respect to health services and facilities in the various States.

§ 100.102 Definitions.

(a) "Act" means the Social Security Act, as amended (42 U.S.C. Chap. 7).

(b) "State" means any of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

(d) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint-stock companies, and insurance companies, a State, or a political subdivision or instrumentality (including a municipal corporation) of a State.

(e) "Health care facility" includes hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers, including freestanding hemodialysis units, intermediate care facilities, and ambulatory surgical facilities, but does not include Christian Science sanatoriums operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts. For purposes of this paragraph:

(1) The term "hospital" means an institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term does not include psychiatric and tuberculosis hospitals.

(2) The term "psychiatric hospital" means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.

(3) The term "tuberculosis hospital" means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis.

(4) The term "skilled nursing facility" means an institution or a distinct part of an institution which is primarily engaged in providing to inpatients

skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(5) The term "intermediate care facility" means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical condition require health-related care and services (above the level of room and board).

(6) The term "ambulatory surgical facility" means a facility, not a part of a hospital, which provides surgical treatment to patients not requiring hospitalization. Such term does not include the offices of private physicians or dentists, whether for individual or group practice.

(f) "Health maintenance organization" means a public or private organization, organized under the laws of any State, which

(1) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: Usual physician services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(2) Is compensated (except for copayments) for the provision of the basic health care services listed in paragraph (f)(1) of this section to enrolled participants on a predetermined periodic rate basis; and

(3) Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

[38 FR 31381, Nov. 13, 1973, as amended at 42 FR 4024, Jan. 21, 1977]

§ 100.103 Expenditures covered.

Any capital expenditure proposed by or on behalf of any health care facility or health maintenance organization, the obligation for which is incurred by or on behalf of a health care facility or health maintenance organization after December 31, 1972, or after the effective date of the agreement entered into pursuant to § 100.104 by the Secretary and the State in which the health care facility or health maintenance organization is located (which effective date may, at the option of the State, be earlier than the date on which such agreement is entered into where the Secretary finds that the procedure utilized by the State for review of proposed capital expenditures as of such earlier date satisfies the requirements of section 1122 and this subpart), whichever is later, is subject to this subpart: *Provided, that,* In the case of a health care facility providing health care services as of December 18, 1970, which on such date is committed to a formal plan of expansion or replacement, this subpart shall not apply with respect to such expenditures as may be made or such obligations as may be incurred for capital items included in such plan where preliminary expenditures toward the plan of expansion or replacement (including payments for studies, surveys, designs, plans, working drawings, specifications, and site acquisition, essential to the acquisition, improvement, expansion, or replacement of the health care facility or equipment concerned) of $100,000 or more, had been made during the three-year period ended December 17, 1970.

(a)(1) For purposes of this subpart, a "capital expenditure" is an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by the facility as its own contractor), which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which (i) exceeds $100,000, or (ii) changes the bed capacity of the facility with respect to which such expenditure is made, or (iii) substantially changes the services of the facility with respect to which such expenditure is made.

(2)(i) For purposes of paragraph (a)(1)(i) of this section, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, or replacement of the plant and equipment with respect to which such expenditure is made shall be included in determining whether such expenditure exceeds $100,000.

(ii) For purposes of paragraph (a)(1)(i) of this section, where the estimated cost of a proposed project, including cost escalation factors appropriate to the area in which the project is located, is, within 60 days of the date on which the obligation for such expenditure is incurred, certified by a licensed architect or engineer to be $100,000 or less, such expenditure shall be deemed not to exceed $100,000 regardless of the actual cost of such project: *Provided, that*, In any such case where the actual cost of the project exceeds $100,000, the health care facility or health maintenance organization on whose behalf such expenditure is made shall provide written notification of such cost to the designated planning agency not more than 30 days after the date on which such expenditure is incurred. Such notification shall include a copy of the certified estimate.

(iii) For purposes of paragraph (a)(1)(ii) of this section, a capital expenditure which "changes the bed capacity" of a facility means a capital expenditure which results in any increase or decrease in licensed capacity under applicable State or local law, or, if there is no such law, the number of beds in a given facility as of January 1, 1973, as determined by the designated planning agency.

(iv) For purposes of paragraph (a)(1)(iii) of this section, a capital expenditure which "substantially changes the services" of a facility means a capital expenditure which results in the addition of a clinically related (i.e., diagnostic, curative, or rehabilitative) service not previously provided in the facility or the termination of such a service which had previously been provided in the facility. The addition of computed tomographic (CT) scanner services not previously provided in or through the facility is a substantial change of services within the meaning of this subparagraph, whether these services are provided through a fixed or mobile CT scanner. The addition of CT full-body scanner services is included in the previous sentence if it is added to or replaces existing CT head scanner services.

(v) Any change in a proposed capital expenditure which itself meets the criteria set forth in this paragraph, shall, for purposes of this subpart, be deemed a capital expenditure; *Provided*, That an increase or decrease in the cost of a proposed capital expenditure which increase or decrease is not related to a change in bed capacity or a substantial change in services may, at the option of the designated planning agency, be exempt from review under this subpart.

(b) Where a person obtains, under lease or comparable arrangement, or through donation, any facility or part thereof, or equipment for a facility, the expenditure for which would have been considered a capital expenditure and subject to exclusion from reimbursement under titles V, XVIII, and XIX of the Act pursuant to this subpart if the person had acquired it by purchase, such acquisition shall be deemed a capital expenditure by or on behalf of such facility and the Secretary shall, subject to section 1122(d) of the Act:

(1) In the case of a lease or comparable arrangement, (i) in computing such person's rental expense, in determining the Federal payments to be made under such titles V, XVIII, and XIX with respect to services furnished in such facility, deduct the amount which in his judgment is a reasonable equivalent of the amount that would have been excluded if the person had acquired such facility or equipment by purchase; and

(ii) In computing such person's return on equity capital, deduct any amount deposited under the terms of the lease or comparable arrangement; and

(2) In the case of a donation which is carried by such person as a capital asset, exclude from reimbursement for services provided under titles V, XVIII, and XIX any amount claimed for depreciation on such facility or equipment, and other costs related to its acquisition.

(c) Obligation: An obligation for a capital expenditure shall be deemed to have been incurred by or on behalf of a health care facility or health maintenance organization.

(1) When an enforceable contract is entered into by such facility or organization or by a person proposing such capital expenditure on behalf of such facility or organization for the construction, acquisition, lease or financing of a capital asset; or

(2) Upon the formal internal commitment of funds by such facility or organization for a force account expenditure which constitutes a capital expenditure; or

(3) In the case of donated property, as described in paragraph (b) of this section the date on which the gift is completed in accordance with applicable State Law.

(d) A determination by a designated planning agency designated in the Agreement described in § 100.104 that a proposed expenditure is not a capital expenditure within the meaning of section 1122 of the Act and this subpart, or that it falls within the exemption described in § 100.103, or that it is otherwise not subject to review under section 1122 of the Act, shall be binding upon the Secretary. A determination by such an agency that a proposed expenditure is a capital expenditure subject to review under section 1122 and this subpart may be appealed, by the person proposing such expenditure, to the Secretary. Such appeal may be made at any time, in such form and manner as the Secretary may prescribe. During the pendency of such appeal, the running of all time periods specified in § 100.106 shall be suspended, except that nothing in this paragraph shall affect the requirement that written notice of the intention to make a capital expenditure subject to this subpart must be received by the designated planning agency not less than 60 days prior to the date on which the expenditure is incurred.

(Sec. 1122, Social Security Act, 86 Stat. 1386 (42 U.S.C. 1320a-1); Sec. 1102, Social Security Act, 49 Stat. 647, as amended (42 U.S.C. 1302))

[38 FR 31381, Nov. 13, 1973, as amended at 44 FR 24429, Apr. 25, 1979]

§ 100.104 Agreement: general.

The Secretary, after consultation with the Governor (or other chief executive officer) and with appropriate public officials, shall make an Agreement with any State which is able and willing to enter into such an agreement under which a designated planning agency (which shall be an agency described in § 100.105) will submit to the Secretary, together with such supporting materials as the Secretary may require, the following:

(a) With respect to each capital expenditure proposed by or on behalf of a health care facility or health maintenance organization in such State, the findings of such designated planning agency as to whether

(1) The designated planning agency or any other agency described in § 100.105 had been given notice of such proposed capital expenditure (in accordance with such procedure or in such detail as may be required pursuant to § 100.106) at least 60 days prior to obligation for such expenditure; and

(2) Such expenditure is or is not consistent with the standards, criteria, or plans developed pursuant to the Public Health Service Act (or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963) to meet the need for adequate health care facilities in the area covered by the plan or plans so developed.

(i) In reaching such findings, the designated planning agency shall consult with, and take into consideration the findings and recommendations of, the other agencies described in § 100.105.

(ii) Where the designated planning agency finds that such expenditure is not consistent with such standards, criteria, or plans, it shall submit to the Secretary the findings and recommendations of all such other agencies with which it has consulted.

(b) With respect to each proposed capital expenditure which is found by the designated planning agency to be not consistent with the standards, criteria, or plans described in paragraph (a) of this section, its recommendation as to whether the Secretary should either

(1) Exclude, in determining the Federal payments to be made under titles V, XVIII, and XIX of the Act with respect to services furnished in the health care facility or health maintenance organization for which such capital expenditure is made, expenses related to such capital expenditure (in accordance with section 1122(d)(1) of the Act); or

(2) Not exclude such expenses, on the ground that such facility or organization has demonstrated proof of capability to provide comprehensive health care services efficiently, effectively, and economically, and that such an exclusion would discourage the operation or expansion of such facility or organization, or of any facility of such organization.

(c) With respect to each proposed capital expenditure which is found by any other agency described in § 100.105 to be not consistent with the standards, criteria, or plans described in paragraph (a) of this section within the field of responsibilities of such other agency, the findings and recommendations of such other agency.

(d) With respect to each proposed capital expenditure as to which the designated planning agency reaches a finding contrary to that reached by the local area planning agency described in § 100.105(a)(3), a statement of the reasons for such a contrary finding.

§ 100.105 Agreement; designated agency.

(a) The designated planning agency designated in the Agreement shall be one of the following:

(1) The State agency designated or established pursuant to section 314(a) of the Public Health Service Act as the sole agency for administering or supervising the administration of the State's health planning functions under the plan developed pursuant to such section 314(a).

(2) The State agency designated pursuant to section 604(a) of the Public Health Service Act as the sole agency for the administration of the State plan developed pursuant to Title VI of the Public Health Service Act.

(3) The public or nonprofit private agency or organization responsible for the comprehensive regional, metropolitan area, or other local area plan or plans referred to in section 314(b) of the Public Health Service Act covering the area in which the health care facility or health maintenance organization proposing such capital expenditure is or is proposed to be located or, if there is no such agency covering such area, such other public or nonprofit private agency or organization which is found by the State agency referred to in paragraph (a)(1) of this section and by the Secretary to be performing similar functions.

(b) The designated planning agency shall have a governing body or advisory board at least half of whose members represent consumer interests.

§ 100.106 Agreement; procedures for agency review.

(a) The Agreement shall provide for the following notification and review procedures:

(1) The designated planning agency shall establish, maintain, and disseminate to all health care facilities and health maintenance organizations within the State procedures under which timely written notice of the intention to make a capital expenditure subject to this subpart is required to be given (i) to the designated planning agency, in which case such agency shall distribute copies of such notice to those other agencies described in § 100.105 whose respective fields of responsibility cover the proposed expenditure, or (ii) simultaneously to the designated planning agency and to those other agencies described in § 100.105 whose respective fields of responsibility cover the proposed expenditure. Such notice shall set forth the date on which the obligation is expected to be incurred, and must be received by the designated planning agency not less than 60 days prior to such date.

(2) Such notice shall be submitted in such form and manner and shall contain such information as may be required by the designated planning agency to meet the needs of all the agencies whose respective fields of re-

sponsibility cover the proposed expenditure. The designated planning agency shall promptly publicize its receipt of such notice through local newspapers and public information channels.

(3) If the notice under this paragraph is found by the designated planning agency to be incomplete, such agency shall notify the person proposing the capital expenditure within 15 days of its receipt of such incomplete notice, advising such person of the additional information required. Where such timely notification of incompleteness is provided, the period within which the agency is required to notify the person proposing such expenditure that such expenditure is not approved, as required by section 1122(d)(1)(B)(i) of the Act and paragraph (a)(4) of this section, shall run from the date of receipt by the agency of a notice containing such additional information.

(4) Except as provided in paragraph (a)(3) of this section, the designated planning agency shall, prior to the date set out in the written notice of intention submitted pursuant to paragraph (a)(1) of this section as the expected date for the obligation of the proposed expenditure (but, subject to the provisions of paragraph (a)(3) of this section in no event later than 90 days after the receipt of such notice unless the person proposing the capital expenditure agrees to a longer period), provide written notification to the person proposing such capital expenditure (i) that such capital expenditure has been determined by such agency to be in conformity with the standards, criteria and plans described in § 100.104(a)(2); or (ii) that such agency has elected not to review the proposed capital expenditure (which election shall be equivalent to a determination by such agency that such expenditure is in conformity with such standards, criteria, and plans), in which event the designated planning agency shall notify the Secretary of its reasons for electing not to review the proposed capital expenditure; or (iii) that such agency after having consulted with, and taken into consideration the findings and recommendations of, the other agencies described in § 100.105 (to the extent that such proposed capital expenditure is within the respective fields of responsibility of such other agencies), has determined that the proposed capital expenditure would not be in conformity with the standards, criteria, or plans described in § 100.104(a)(2). The failure of the designated planning agency to provide any such notification within the time limitations set forth above shall have the effect of a determination described in paragraph (a)(4)(i) of this section. The notification described in paragraph (a)(4)(iii) of this section shall be accompanied by a statement of the designated planning agency's proposed recommendation to the Secretary and the reasons therefor, a summary of the findings and recommendations of the other agencies with which such agency has consulted pursuant to paragraph (a)(4)(iii) of this section and shall provide an opportunity for a fair hearing with respect to the findings and recommendations of the designated planning agency at the request of the person proposing such capital expenditure.

(5) Copies of the findings and recommendations of the designated planning agency shall also be sent to the other agencies consulted, and shall be publicized through local newspapers and public information channels.

(b) Any person proposing a capital expenditure may withdraw his previously filed notice of proposed capital expenditure, without prejudice, by filing simultaneous written notification of such withdrawal with those agencies to which he gave notification pursuant to paragraph (a)(1) of this section, at any time prior to his receipt of notice pursuant to paragraph (a)(4) (i), (ii), or (iii) of this section.

(c) In addition to any other hearing which may be provided by an agency described in § 100.105 in connection with the review of a proposed capital expenditure under this subpart, the Agreement shall provide that the designated planning agency will grant to a person proposing a capital expenditure an opportunity for a fair hearing with respect to the findings and recommendations of the designated planning agency, and will establish and maintain procedures for such appeal. Such procedures shall include the following:

(1) The request for a hearing must be made in writing, to the designated planning agency, within 30 days after the date on which the person proposing the capital expenditure receives notice of an adverse finding or recommendation of the designated planning agency.

(2) The hearing shall be commenced within 30 days after receipt of the request described in paragraph (c)(1) of this section (or later, at the option of the person requesting the hearing), and shall be conducted in accordance with the applicable requirements of State law and by such agency or person, other than the designated planning agency, as the Governor (or other chief executive officer of the State) may designate for that purpose: *Provided,* That no agency which or person who has taken part in any prior consideration of or action upon the proposed capital expenditure may conduct such hearing.

(i) The hearing shall be open to the public and shall be publicized through local newspapers and public information channels.

(ii) The person proposing the capital expenditure, the other agencies described in § 100.105, and other interested parties, including representatives of consumers of health services, shall be permitted to give testimony and present arguments at the hearing.

(iii) A record of the proceedings shall be kept in accordance with the requirements of applicable State law and copies of such record together with copies of all documents received in evidence, shall be available to the public for inspection and copying: *Provided,* That any person who requests copies of such material may be required to bear the costs thereof.

(3) As soon as practicable, but not more than 45 days after the conclusion of a hearing, the hearing officer shall notify the person who requested the hearing, the designated planning agency, the other agencies described in § 100.105 who participated in the hearing, and other interested parties at the discretion of the hearing officer, of his decision and the reasons therefor. Such decision shall be publicized through local newspapers and public information channels. In the event that the hearing officer fails to provide notice as required above within 45 days after the conclusion of a hearing, such failure to provide notice shall have the effect of a finding that the proposed capital expenditure is in conformity with the standards, criteria, and plans described in § 100.104(a)(2).

(4) Any decision of a hearing officer, arrived at in accordance with this paragraph, shall, to the extent that it reverses or revises the findings or recommendations of the designated planning agency, supersede the findings and recommendations of the designated planning agency: *Provided,* That where judicial review of such decision is obtained, the final decision of the reviewing court, to the extent that it modifies the findings and recommendations of the designated planning agency, shall to such extent supersede the findings and recommendations of the designated planning agency.

(5) To the extent that any decision of a hearing officer pursuant to this paragraph requires that the designated planning agency take further action, such action shall be completed by such date as the hearing officer may specify. Failure by the designated planning agency to complete such action by such date shall have the effect of a finding that the proposed capital expenditure is in conformity with the standards, criteria, and plans described in § 100.104(a)(2).

[38 FR 31381, Nov. 13, 1973, as amended at 38 FR 32789, Nov. 28, 1973]

§ 100.107 Agreement; criteria for agency review.

The Agreement shall set forth the criteria under which the designated planning agency and the other agencies described in § 100.105 shall evaluate proposals for capital expenditures for purposes of this subpart to determine their conformance with the applicable standards, criteria and plans referred to in § 100.104(a)(2). Such criteria, to the extent provided for under such standards, criteria, or plans, shall include the following:

(a) Whether the proposed project is needed or projected as necessary to meet the needs in the community in terms of health services required: *Provided*, That projects for highly specialized services (such as open-heart surgery, renal transplantation, or radiation therapy) which will draw from patient population outside the community in which the project is situated will receive appropriate consideration;

(b) Whether the proposed project can be adequately staffed and operated when completed;

(c) Whether the proposed capital expenditure is economically feasible and can be accommodated in the patient charge structure of the health care facility or health maintenance organization without unreasonable increases; and

(d) Whether the project will foster cost containment or improved quality of care through improved efficiency and productivity, including promotion of cost-effective factors such as ambulatory care, preventive health care services, home health care, and design and construction economies, or through increased competition between different health services delivery systems.

§ 100.108 Determination by the Secretary.

(a) Except as provided in paragraph (b) of this section, if the Secretary determines that (1) the designated planning agency has not been given timely notice of intention to make a capital expenditure in accordance with § 100.106, or (2) that the designated planning agency has, in accordance with the requirements of section 1122 of the Act and this subpart, submitted to the Secretary its finding that such expenditure is not consistent with the standards, criteria, or plans described in § 100.104(a)(2) then, for such period as he deems necessary to effectuate the purpose of section 1122 of the Act, he shall, in determining the Federal payments to be made under titles V, XVIII, and XIX of the Act to such health care facility or health maintenance organization, exclude expenses related to such capital expenditure.

(b) Notwithstanding the provisions of paragraph (a) of this section, if the Secretary, after submitting the matters involved to the National Advisory Health Council on Comprehensive Health Planning Programs (established pursuant to section 316 of the Public Health Service Act, 42 U.S.C. 247a) and after taking into consideration the recommendations of the designated planning agency and the other agencies described in § 100.105 with respect to such expenditure, determines that an exclusion of expenses related to any capital expenditure of any health care facility or health maintenance organization would discourage the operation or expansion of such facility or organization, or of any facility of such organization, which has demonstrated to his satisfaction proof of capability to provide comprehensive health care services efficiently, effectively, and economically, or would otherwise be inconsistent with the effective organization and delivery of health services or the effective administration of titles V, XVIII, or XIX of the Act, he shall include such expenses in Federal payments under such titles.

(c) Upon making a determination under this section the Secretary will promptly notify the person proposing such capital expenditure, the designated planning agency, and the other agencies described in § 100.105 with which the designated planning agency has consulted, of such determination and the basis for such determination.

(d) Any person dissatisfied with a determination by the Secretary under section 1122 of the Act or this subpart with respect to a particular capital expenditure may, within six months following the date of such determination, request the Secretary to reconsider such determination.

(1) Such request for reconsideration shall be in writing, addressed to the Secretary of Health and Human Services or to any officer or employee of the Department of Health and Human Services to whom the Secretary has delegated responsibility to receive such requests, and shall set forth the grounds based upon the record of the proceedings and any issues of law, upon which such reconsideration is requested.

(2) Reconsideration will be based upon the record of the proceedings,

which shall consist of the findings, recommendations and supporting materials submitted to the Secretary by the designated planning agency (including the findings and recommendations of other agencies) which relate to the findings and recommendations involved, the record of the hearing provided by the designated planning agency, if any, and of any judicial proceedings, the materials submitted in connection with such request, and such comments as the Secretary may request from the designated planning agency.

(3) Notice of any reconsidered determination under this paragraph shall be sent to the designated planning agency and the person requesting such reconsideration.

(e) A determination by the Secretary is, under section 1122 of the Act, not subject to administrative or judicial review.

NOTE: Where the Secretary makes the determination described in 42 CFR 100.108(a)(1), he will follow the following policy in establishing the time period during which reimbursement will be withheld:

(1) Where the health care facility or health maintenance organization by or on behalf of which the expenditure was made demonstrates to the satisfaction of the Secretary that a reasonable effort had been made to determine from the designated planning agency whether the expenditure was subject to review, and the designated planning agency had not informed the facility or organization within a reasonable period of time that the proposed expenditure was subject to review, the Secretary will not withhold reimbursement related to the capital expenditure.

(2) Where the designated planning agency has, in accordance with requirements of section 1122 of the Act and its regulations (42 CFR Part 100), submitted to the Secretary its finding that such expenditure is not consistent with the standards, criteria, or plans described in § 100.104(a)(2) of the regulations, and where paragraph (1) above is not applicable, the Secretary will withhold all reimbursement related to the capital expenditure: *Provided*, That where the designated planning agency, in accordance with § 100.109(c), submits to the Secretary a revised funding in accordance with paragraph (c)(2) of that section, the Secretary will apply the provisions of paragraph (3) or paragraph (4) below, whichever is applicable.

(3) Where (i) the designated planning agency submits to the Secretary its finding that for the proponent to comply with the requirement of § 100.106 for timely notice of intent to incur the obligation for a capital expenditure, which capital expenditure was not for the purpose of providing a new service or expanding the capacity of the health care facility or health maintenance organization to offer an existing service, would have placed in jeopardy the health or the safety of the patients of the facility or organization, and that the proponent gave such notice as, in the opinion of the designated planning agency, was reasonable under the circumstances, and (ii) if the facility or organization submitted to the designated planning agency within 60 days following the date of the obligation for the expenditure or 90 days following the date of publication of this policy in the FEDERAL REGISTER, whichever is later, a complete application and (iii) the designated planning agency submits to the Secretary its finding that the capital expenditure is consistent with the standards, criteria, and plans described in § 100.104(a)(2) which apply at the time of the review by the designated planning agency, the Secretary will not withhold reimbursement related to the capital expenditure.

(4) Where the designated planning agency submits to the Secretary its finding that the capital expenditure is consistent with the standards, criteria, and plans described in § 100.104(a)(2) which apply at the time of the review by the designated planning agency, but the provisions of neither paragraph (1) nor paragraph (3) above apply, the Secretary will withhold reimbursement related to the capital expenditure for a period of one year.

[38 FR 31381, Nov. 13, 1973, as amended at 42 FR 4848, Jan. 26, 1977]

§ 100.109 Continuing effect of determinations.

(a) Except in the case of a long-term construction plan of the type described in paragraph (b) of this section, where the designated planning agency has found that a proposed capital expenditure is in conformity with the standards, criteria, and plans described in § 100.104(a)(2), the obligation for such capital expenditure shall be incurred not more than one year following the date of such finding, or such shorter period as may be required by applicable State law: *Provided*, That in the absence of any State law to the contrary, the designated planning agency may, pursuant to a showing of good cause by the person proposing such expenditure, extend the period during which such obligation must be incurred for up to an additional six months. If no such obligation is incurred within such period, the designated planning agency's approval shall, for purposes of this subpart, be deemed to be terminated upon the expiration of such period.

(b) In the case of any plan for capital expenditures proposed by or on behalf of a health care facility or health maintenance organization under which a series of obligations for capital expenditures for discrete components of the plan is to be incurred over a period longer than one year, the designated planning agency may review and approve or disapprove, for purposes of this subpart, those of such capital expenditures which it estimates will be incurred within three years following the date of such approval or disapproval.

(c)(1) In any case in which the Secretary has determined pursuant to a finding by the designated planning agency that a proposed capital expenditure is not in conformity with the standards, criteria, or plans described in § 100.104(a)(2), that expenses related to such capital expenditure shall not be included in determining Federal payments under titles V, XVIII, and XIX of the Act the health care facility or health maintenance organization to whom such payments are made shall be entitled, upon its request to the designated planning agency in such form and manner and supported by such information as such agency may require, to a reconsideration by the designated planning agency of such finding:

(i) Whenever there is a substantial change in existing or proposed health facilities or services, of the type proposed, in the area served by such facility or organization; or

(ii) Upon a substantial change in the need for facilities or services, of the type proposed, in the area served by such facility or organization, as reflected in the standards, criteria or plans referred to in § 100.104(a)(2); or

(iii) At any time following the expiration of three years from the date of the finding of the designated planning agency or of its last reconsideration of such finding pursuant to this paragraph, whichever is later.

(2)(i) If, upon reconsideration of its finding pursuant to this paragraph, and after consulting with and taking into consideration the findings and recommendations of the other agencies described in § 100.105, the designated planning agency finds that the facilities or services provided by such capital expenditure are in conformity with the standards, criteria, and plans described in § 100.104(a)(2) it shall promptly so notify the Secretary and the person submitting such request.

(ii) If the designated planning agency, upon such reconsideration, reaffirms its previous finding, the procedure set forth in § 100.106 following an initial determination shall be followed.

(3) Upon notification by a designated planning agency of a revised finding in accordance with paragraph (c)(2) of this section, the Secretary will include, in determining future payments under titles V, XVIII, and XIX of the Act, expenses related to such capital expenditure. Such expenses will be included for periods following the date of such notification only, and amounts previously excluded shall not be taken into account in determining Federal payments under titles V, XVIII, and XIX of the Act.

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AUTHORITY: Sec. 215, 58 Stat. 690, (42 U.S.C. 216); secs. 1301-1316, as amended, 90 Stat. 1945-1960 (42 U.S.C. 300e-300e-15), unless otherwise noted.

SOURCE: 40 FR 37311, Oct. 18, 1974, unless otherwise noted.

EDITORIAL NOTE: For a document giving notice of statutory amendments which affect 42 CFR Part 110, see 46 FR 45694, Sept. 14, 1981, and 46 FR 51246, Oct. 19, 1981.

Subpart A—Requirements for a Health Maintenance Organization

AUTHORITY: Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318 of the Public Health Service Act, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17).

SOURCE: 45 FR 72528, Oct. 31, 1980, unless otherwise noted.

§ 110.101 Definitions.

As used in this part: "Act" means the Public Health Service Act.

"Basic health services" means health services described in § 110.102(a).

"Community rating system" means a system of fixing rates of payments for health services which meets the requirements of § 110.105(a)(3).

"Comprehensive health services" means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§ 110.102(a)(1));

(2) Outpatient services and inpatient hospital services (§ 110.102(a)(2));

(3) Medically necessary emergency health services (§ 110.102(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 110.102(a)(6)).

"Direct service contract" means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

"Full-time student" means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

"Health maintenance organization" (HMO) means a legal entity which provides or arranges for the provision of basic and supplemental health services to its members in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the Act and the regulations of this subpart.

"Health professionals" means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

"Individual practice association" (IPA) means a partnership, association, corporation, or other legal entity which delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement shall provide:

(1) That these health professionals shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

"Medical group" means a partnership, association, corporation, or other group:

(1) Which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services or which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

"Medical group members" means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

"Medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services. The Secretary will designate these areas as described in § 110.203(d).

"Member," when used in connection with an HMO, means an individual who has entered into a contractual relationship with the HMO or on whose behalf a contractual arrangement has been entered into with the HMO by a subscriber under which the HMO assumes the responsibility for the provision to the member of basic health services and such supplemental health services as may be contracted for.

"Nonmetropolitan area" means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

"Party in interest" means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

"Policymaking body" of an HMO means a board of directors, governing body, or other body of individuals which has the authority to establish policy for the HMO.

"Qualified HMO" means an HMO found by the Secretary to be qualified within the meaning of Section 1310 of the Act and Subpart F of this part.

"Rural area" means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, "Number of Inhabitants," Table VI, "Population of Places," and not listed as an urbanized area in Table XI, "Population of Urbanized Areas" of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"Service area" means the geographic area as defined through zip codes, census tracts, or other geographic subdivisions, found by the Secretary to be the area within which the HMO provides or arranges for basic and supplemental health services that are available and accessible to its members as required by section 1301(b)(4) of the Act.

"Significant business transaction" means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

"Staff of the HMO" means health professionals who are employees of the HMO and who:

(1) Provide services to HMO members at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to members of the HMO the health services which the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO;

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

"Subscriber" means a member who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

"Supplemental health services" means the health services described in § 110.103(a).

"Unusual or infrequently used health services" means: (1) Those health services which are projected to involve fewer than 1 percent of the encounters per year for the entire HMO membership, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982]

§ 110.102 Health benefits plan: Basic health services.

(a) An HMO shall provide or arrange for the provision of basic health services to its members as needed and without limitations as to time and cost other than those prescribed in the Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which shall be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which shall include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital; (ii) inpatient hospital services, which shall include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma; (iii) outpatient services and inpatient hospital services shall include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its members on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per member per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs shall include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which shall be made available to members and shall include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 110.103 as a supplemental health service in the basic health services which it provides or arranges for its members for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of this subpart, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the member is legally entitled to services and for which facilities are reasonably available to this member;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services which are unusual and infrequently provided and not necessary for the protection of individual health, as approved by the Secretary upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis which do not include all the basic health services set forth in paragraph (a) of this section or which are limited as to time and cost except in a manner prescribed by this part.

§ 110.103 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its members any health service which is not included as a basic health service under § 10.102(a). These health services may be limited as to time and cost.

(b) An HMO shall determine the level and scope of supplemental health services included with basic health services provided to its members for a basic health services payment or those services offered to its members as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982]

§ 110.104 Providers of basic and supplemental health services.

(a)(1) The HMO shall provide that the services of health professionals which are provided as basic health services will, except as provided in paragraph (e) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, the Secretary approves the sharing as being consistent with the purposes of section 1310(b) of the Act.

(3) After the 4 year period beginning with the month following the month in which an HMO becomes a qualified

HMO, an entity which meets the requirements of the definition of medical group in § 110.101, except for subdivision (3)(i) of that definition, may be considered a medical group if the Secretrary determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of the Secretary that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the "substantial responsibility" requirement of subdivision (3)(i) of the definition of "medical group" in § 110.101. The HMO shall update the plan annually and shall demonstrate to the satisfaction of the Secretary that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or

(ii) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because (A) the HMO serves a non-metropolitan or rural area as defined in § 110.101, or (B) the entity is a multi-speciality group which provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of members to require utilization of at least 35 percent of the entity's services.

(b) HMOs shall include: (1) In their contracts with medical groups or IPAs for the provision of basic and supplemental health services at least the following:

(i) A description of responsibilities of the parties to the contract;

(ii) The agreed upon compensation for services;

(iii) An agreement that the medical group or IPA, its members and the health professionals contracting with it, will look solely to the HMO for compensation for services provided to the HMO's members. This agreement shall not extend to copayments or payments for supplemental health services on other than a prepaid basis, but the contracting party shall not assert any claim for compenstion against members in excess of these copayments or payments for these supplemental health services;

(iv) Provisions requiring participation by health professionals in quality assurance activities;

(v) A description of mechanisms, such as risk sharing, financial incentives, or other incentives, to be applied to monitor utilization and to control costs of basic and supplemental health services and to achieve utilization goals; and

(vi) Assurances that medical groups and IPAs, or the health professionals associated with them, will be protected by professional liability coverage, either through insurance or self-insurance;

(2) In their contracts with health professionals for the provision of basic and supplemental health services (except for unusual or infrequently used services) at least the provisions described in paragraphs (b)(1) (i), (ii), (iii), and (iv) of this section.

(c) Staff model HMOs shall have effective procedures to monitor utilization and to control cost of basic and supplemental health services, and to achieve utilization goals.

(d) Paragraph (a) of this section does not apply to the provision of the services of a physician—

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the member other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(e) Supplemental health services shall be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(f) Each HMO shall:

(1) Pay the provider, or reimburse its members for the payment of reasonable charges for basic health services (or supplemental health services which the HMO agreed to provide on a prepayment basis) for which its members have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from members for reimbursement for the provision of health services described in paragraph (g)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its members on procedures to be followed to secure these health services.

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982]

§ 110.105 Payment for basic health services.

(a) *Basic health services payment.* Each HMO shall provide or arrange for the provision of basic health services for a basic health services payment which:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its members, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or membership in the HMO, an HMO may not impose copayment charges on any subscriber (or members covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or members) in that calendar year total 100 percent of the total annual premium cost which that subscriber (or members) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or members) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue which would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers shall be calculated to yield revenues substantially equivalent to the prod-

uct of the total number of members (or subscribers) expected to be enrolled from the group and the per-member-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this subparagraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment which are established for new enrollments or re-enrollments and which do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it shall:

(i) Classify all of the members of the organization into classes based on factors which the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(ii) Determine its revenue requirements for providing services to the members of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. The Secretary will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former Members and their Dependents") of Title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 ("Health Insurance") of Title 5 ("Government Organization and Employees"), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to the Secretary of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its members, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.* (1) In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided a member who is a full-time student at an accredited institution of higher education.

(d) *Charges for benefits covered by workers' compensation law or insurance policy.* The requirements respecting the basic health services payment do not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workers' compensation law or an insurance policy, but only to the extent these benefits apply to these services.

(1) For the provision of services for an illness or injury for which a member is entitled to benefits under a workers' compensation law, the HMO may, if authorized by this law, charge or authorize the provider of the services to charge, in accordance with the charges allowed under the law: (i) The insurance carrier, employer, or other entity which under the law is to pay for the provision of the services, or (ii) the member, to the extent that the member has been paid under the law for the services.

(2) For the provision of services for an illness or injury for which a member is entitled to benefits under an insurance policy, an HMO may charge or authorize the provider of the services to charge: (i) The insurance carrier under the policy, or (ii) the member, to the extent that the member has been paid under the policy for the services.

(e) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable which are in arrears.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982]

§ 110.106 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 110.103 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its members for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments which are fixed on a prepayment basis, however, shall be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student at an accredited institution of higher education. In the case of an HMO which provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(c) When the HMO provides supplemental health services on a prepayment basis for which the member is entitled to benefits under a workers' compensation law or an insurance policy, the HMO may take the actions described in § 110.105(d)(1) or (2) (respecting charges for basic health services which are benefits under a workers' compensation law or insurance policy) as appropriate.

§ 110.107 Availability, accessibility, and continuity of basic and supplemental health services.

Within the HMO's service area, basic health services and those supplemental health services for which members have contracted shall be:

(a) Provided or arranged for by the HMO;

(b) Available and accessible to each of the HMO's members with reasonable promptness with respect to:

(1) Geographic location, hours of operation, and provisions for after-hours services (medically necessary emergency services must be available and accessible 24 hours a day, 7 days a week), except that an HMO which has a serv-

ice area located wholly in a non-metropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency care service and if there is an insufficient number of providers of that basic health service within the service area who will provide that service to members of the HMO; and

(2) Staffing patterns within generally accepted norms for meeting the projected membership needs; and

(c) Provided in a manner which assures continuity, including but not limited to:

(1) Provision of a health professional who is primarily responsible for coordinating the member's overall health care; and

(2) Development of a health (including medical) recordkeeping system through which pertinent information relating to the health care of the patient is accumulated and is readily available to appropriate professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19340, May 5, 1982]

§ 110.108 Organization and operation.

(a) *Fiscally sound operation and administrative and managerial arrangements.* (1) Each HMO shall have a fiscally sound operation as demonstrated by:

(i) Total assets being greater than total unsubordinated liabilities. In this evaluation, loan funds awarded or guaranteed under section 1305 of the Act are not included as liabilities, and if the funds have not been disbursed to the HMO by the Secretary or by an escrow agent, they are not included as assets;

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due;

(iii) A net operating surplus. If the HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year, does not a have positive net worth, or is seeking a Federal loan or loan guarantee under sections 1305 or 1305A of the Act, the HMO shall submit a financial plan satisfactory to the Secretary to achieve net operating surplus within available fiscal resources. This plan shall include:

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds' statements; and

(D) Balance sheets;

(iv) A plan for handling insolvency which allows for continuation of benefits for the duration of the contract period for which payment has been made, continuation of benefits to members who are confined on the date of insolvency in an inpatient facility until their discharge, and payments to unaffiliated providers for services rendered;

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO;

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by the Secretary to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

(vii) A plan to maximize its enrollment in a manner consistent with sound management.

(2) Each HMO shall have administrative and mangerial arrangements satisfactory to the Secretary, as demonstrated by at least the following:

(i) A policymaking body which exercises oversight and control over the HMO's policies and personnel to assure that management actions are in the best interest of the HMO and its membership; and

(ii) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO. At a minimum, the HMO shall be managed by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(3) *Protection of members.* (i) Each HMO shall adopt at least one of the

following arrangements to protect its members from incurring liability for payment of any fees which are the legal obligation of such organization:

(A) A contractual arrangement with any hospital regularly used by the members of the HMO prohibiting the hospital from holding any member liable for payment of any fees which are the legal obligation of the HMO;

(B) Insolvency insurance, acceptable to the Secretary;

(C) Adequate financial reserve acceptable to the Secretary;

(D) Other arrangements acceptable to the Secretary to protect members; and

(ii) The requirements of this subparagraph do not apply to an HMO if applicable State law provides the members of the HMO with protection from liability for payment of any fees which are the legal obligation of the HMO.

(b) *Financial risk.* Each HMO shall assume full financial risk on a prospective basis for the provisions of basic health services, except that it may (1) Obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year;

(2) Obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the HMO because medical necessity required their provision before they could be secured through the HMO;

(3) Obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year; and

(4) Make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(c)(1) *Full and fair disclosure.* Each HMO shall prepare a written description of the items listed below. This description shall be written so that it can be easily understood by the average person who might enroll in the HMO. The description of benefits and coverage (items in paragraph (c)(1) (i) and (ii) of this section, respectively, below) may be in general terms if reference is made to a detailed statement of benefits and coverage which is available without cost to any person to whom the opportunity for enrollment in the HMO is offered or who has enrolled in the HMO. Upon request made directly to the HMO or the plan administrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") of a health benefits plan which includes the HMO option, the HMO shall provide the description to any person who is a participant or beneficiary of the plan and who is eligible to elect the HMO option. The items to be included in the written description are the HMO's:

(i) Benefits (including limitations and exclusions);

(ii) Coverage (including a statement of conditions on eligibility for benefits);

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied;

(iv) Rates;

(v) Grievance procedures;

(vi) Service area;

(vii) Participating providers:

(A) If the HMO provides health services through an individual practice association(s), the HMO shall provide the number of member physicians by specialty, and a listing of the hospitals where HMO members will receive basic and supplemental health services; and

(B) If the HMO provides health services other than through an individual practice association, the HMO shall provide for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO members will receive basic and supplemental health services; and

(viii) Financial condition to include at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Broadly representative enrollment.* After providing the written description referred to in paragraph (c)(1) of this section, each HMO shall offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area. In the case of an HMO which has a medically underserved population located in its service area, not more than 75 percent of the HMO members may be enrolled from the medically underserved population unless the area in which that population resides is also a rural area.

(d) *Health status and enrollment.* The HMO shall not expel or refuse to re-enroll any member nor refuse to enroll individual members of a group, on the basis of the health status, health care needs, or age of the member or individual. For purposes of this paragraph, a "group" is an entity which consists of members who enroll in the HMO through a contract or other arrangement which provides for the enrollment of two or more subscribers. Nothing in this subpart prohibits an HMO from requiring that, as a condition of continued eligibility for membership, dependents of a subscriber, upon reaching a specified age, convert to nongroup membership consistent with the terms of § 110.108(g).

(e) *Conversion of membership.* Each HMO shall offer membership on the same terms and conditions as are available to a nongroup subscriber to:

(1) Each subscriber (and his enrolled dependents) leaving a group; and

(2) Each member who would otherwise cease to be eligible for HMO membership because of his or her age or the death or divorce of a subscriber.

(f) *Policymaking body.* (1) In the case of a private HMO, no later than one year after becoming operational as a qualified HMO, at least one-third of the membership of its policymaking body must be members of the HMO who reside in or in proximity to the service area of the HMO. An HMO with regional components and one overall policymaking body must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMO's regional components. HMOs with policymaking bodies consisting of the same individuals must assure that the individuals satisfying the one-third member requirement reside in, or in proximity to, the service area of at least one of the HMOs.

(i) No member having ownership of or financial interest in, or employed by, or gaining financial reward from direct dealings with, the HMO or a plan-affiliated institution or organization, and no members of the immediate family of such member shall be included in the minimum one-third member representation on the policymaking body. However, none of the foregoing prohibits the payments of directors' fees or other similar fees, or interest and dividends derived from membership in an HMO cooperative, to persons serving on the policymaking body.

(ii) There shall be equitable representation on the member portion of the policymaking body of members from the medically underserved populations served by the HMO in proportion to their enrollment relative to the entire enrollment; except that if the membership from these medically underserved populations is at least 5 percent of the total enrollment, then those populations shall not be without representation.

(2) In the case of public HMO, have an advisory board to its policymaking body operating the HMO which board meets the requirements of subparagraph (f)(1) of this section, and to which may be delegated policymaking authority for the HMO.

(g) *Grievance procedures.* Each HMO shall have and use meaningful procedures for hearing and resolving grievances between the HMO (including the staff of the HMO, the medical group, and the IPA) and the members of the HMO. These procedures must assure that: (1) Grievances and complaints will be transmitted in a timely manner to appropriate decisionmaking levels within the HMO which have authority to take corrective action; and (2) appropriate action will be taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Quality assurance program.* Each HMO shall have an ongoing quality assurance program for is health services which:

(1) Stresses health outcomes to the extent consistent with the state of the art;

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services;

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change; and

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services which should have been furnished have not been provided;

(i) *Certification of institutional providers.* Each HMO shall assure that institutional providers through which it provides basic and supplemental health services (1) are certified either under Title XVIII of the Social Security Act (Medicare) in accordance with 42 CFR Part 405 or under Title XIX of the Social Security Act (Medicaid) in accordance with the regulations governing participation of providers in the Medical Assistance Program; or (2) in the case of hospitals, are either accredited by the Joint Commission on Accreditation of Hospitals or certified by Medicare; or (3) in the case of clinical laboratories (except for laboratories exempted from section 353 of the Public Health Service Act by paragraphs (d)(2), (i), or (1) of that section), certified by Medicare or Medicaid or licensed under section 353.

(j) *Reporting and disclosure requirements.* (1) While safeguarding the confidentiality of the doctor-patient relationship, each HMO shall provide an effective procedure to develop, compile, evaluate, and report to the Secretary, to its members, and to the general public, at the times and in the manner the Secretary requires, statistics and other information relating to:

(i) The cost of its operations;

(ii) The patterns of utilization of its services;

(iii) The availability, accessibility, and acceptability of its services;

(iv) To the extent practical, developments in the health status of its members;

(v) Information demonstrating that the HMO has a fiscally sound operation;

(vi) Other matters as the Secretary may require;

(2) Each HMO shall report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time):

(i) A copy of the report, if any, filed with the Department's Health Care Financing Administration containing the information required to be reported by disclosing entities under regulations implementing section 1124 and section 1902(a)(38) of the Social Security Act (see 42 CFR 420.206 and 42 CFR 455.104), respectively; and

(ii) A description of the following significant business transactions between the HMO and a party in interest, and a justification that the costs of these transactions do not exceed the costs which would be incurred if these transactions were to be with someone who is not a party in interest (or if they do, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements):

(A) Sale, exchange, or leasing of property;

(B) Furnishing for consideration of goods, services (including management services), or facilities between the HMO and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical groups, IPAs, or any combination thereof; and

(C) Lending of money and other extension of credit.

(3)(i) Report to the Secretary annually, within 180 days of the end of its fiscal year (unless for good cause shown, the Secretary authorizes an extension of time), a combined financial statement for the organization and such entity if:

(A) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest; or

(B) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

The combined financial statements must display in separate columns the financial information for the HMO and each of these parties in interest. Inter-entity transactions must be eliminated in the consolidated column. These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(ii) The Secretary may, upon a written request from an HMO and for good cause shown, waive the requirement that its combined financial statement include the financial information required in this paragraph with respect to a particular entity.

(k) *Human diginity.* Each HMO shall be organized and operated in a manner intended to preserve human dignity;

(l) *Confidentiality of health records.* Each HMO shall establish adequate procedures to insure confidentiality of its members' health (including medical) records; and

(m) *Referral information.* Each HMO shall make arrangements either directly or through its providers to assure that the HMO or the health professional coordinating the member's overall health care is kept informed about the services provided to its members by referral resources.

(n) *Reporting and Disclosure under ERISA.* Each HMO shall provide each employer or designee (as those terms are defined in § 110.801 of this part) or plan administrator (as that term is defined under the Employee Retirement Income Security Act of 1974, "ERISA") including the HMO option in its employees' health benefits plan, upon request, the information which is necessary to satisfy its reporting and disclosure obligations under ERISA insofar as that HMO is involved.

[45 FR 72528, Oct. 31, 1980, as amended at 46 FR 6355, Jan. 21, 1981; 47 FR 19340, May 5, 1982]

§ 110.109 Prohibited activities.

An HMO may not sell, market or promote, to an individual or group, directly or through arrangements with other entities, health insurance or a health service benefit plan for health benefits which the HMO includes in the prepaid health benefits package offered to that individual or group. In addition, the HMO may not permit its employees to do so in the normal course of their employment.

§ 110.110 Special requirements: Titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the Act, an HMO which otherwise complies with section 1301(b) and section 1301(c) of the Act, and with the applicable regulations of this subpart, and which enrolls members who are entitled to insurance benefits under Title XVIII of the Social Security Act or to medical assistance under a State plan approved under Title XIX of that Act, may still be considered as an HMO, if with respect to its Title XVIII and Title XIX members it provides services and is operated as required by Title XVIII or XIX, as appropriate, and regulations thereunder.

(b) Notwithstanding any inconsistent requirements of this subpart, an HMO which enters into a contract with the Secretary under Title XVIII of the Social Security Act or with a State under Title XIX of that Act shall, with respect to its members entitled to insurance benefits or medical assistance under those titles, comply with the applicable Title XVIII or Title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of Title XVIII or the Title XIX State plan of the State with which it is contracting. Copayment options which are not in accordance with a Title XIX State plan may not be imposed on Title XIX enrollees.

(c) Any grievance procedures authorized under Title XVIII or Title XIX of the Social Security Act are not superseded by the provisions of § 110.108(i).

§ 110.111 Special requirements: Federal employee health benefits program.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of Title 5, United States Code, may be considered as an HMO for purposes of receiving assistance under this Part if with respect to its other members it (a) provides health services in accordance with section 1301(b) of the Act and the applicable regulations of this part and (b) is organized and operated in the manner prescribed by section 1301(c) of the Act and the applicable regulations of this part.

Subpart B—Federal Financial Assistance: General

AUTHORITY: Sec. 215, 58 Stat. 690, (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17).

SOURCE: 44 FR 42076, July 18, 1979, unless otherwise noted.

§ 110.201 To whom do these regulations apply?

The regulations of this subpart apply to the award of grants, loans, and loan guarantees to public or private entities for projects as authorized by sections 1303, 1304, 1305, and 1305A of the Act.

§ 110.202 Definitions.

"Expansion of services" means (1) the addition of any health service not previously provided by or through the HMO, which requires an increase in the facilities, equipment, or health professionals of the HMO, or (2) the improvement or upgrading of existing facilities or equipment, or an increase in the number or categories of health professionals, of the HMO so that the HMO may provide directly services which it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

"Health system agency" means an entity which has been designated in accordance with section 1515 of the Public Health Service Act; and the term "State Health planning and development agency" means an agency which has been designated in accordance with section 1521 of the Act.

"Nonprofit" as applied to a private entity, agency, institution, or organization means a private entity, agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Significant expansion" means (1) a planned substantial increase in membership of the HMO which will require an increase in the number of health professionals serving members of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or (2) a planned expansion of the service area beyond the current service area which would be made possible by the addition of health service delivery facilities and health professionals to serve members at a new site or sites in areas previously without service sites. Only organizations which have been found by the Secretary to be qualified HMOs are eligible to apply for assistance for expansion under sections 1303 and 1304 of the Act.

§ 110.203 What are the requirements for an application?

(a) *Financial information.* In addition to complying with requirements set forth in the appropriate forms for applying for financial assistance under this part, applicants must submit an audited full financial statement unless exempted by the Secretary. Except for an application under section 1303 of the Act, an applicant whose financial statement shows unobligated cash assets which presumably could be used to conduct all or part of the project or undertaking for which application is made must also submit a detailed statement satisfactory to the Secretary stating why the unobligated cash assets of the applicant are not available or are inadequate for the planned project. (The only assets of the applicant which need be considered in this regard are assets other than those to be used to meet the applicant's contribution requirements and other than those the obligation of which for the project the Secretary determines would jeopardize the applicant's fiscal soundness.) An applicant for a loan or loan guarantee shall also submit a written verification from at least two public or private lending agencies or institutions demonstrating that, after a formal request:

(1) Funds have been denied in the amount requested in the application; or

(2) Funds in the amount requested in the application are available only at an interest rate in excess of those currently in effect for the loan or loan guarantee program, as appropriate, on the date of the application. On the basis of the information submitted, the Secretary will determine whether the applicant would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for.

(b) *Assurances.* Each application must contain the following assurances, as appropriate, which are binding on successors, assignees, and transferees of the applicant, as well as the applicant:

(1) In the case of an application for assistance under section 1303 of the Act, if the survey or other activity supported demonstrates that the development and operation or the expansion of the operation of an HMO is feasible, the applicant will be, or will form, or expand the operation of, as appropriate, and HMO;

(2) In the case of an application for assistance under section 1304 of the Act, the applicant will develop and operate or expand the operation of, as the case may be, an HMO;

(3) When operational as an HMO, the applicant will (i) provide basic health services to its members, (ii) provide these services in the manner prescribed by section 1301(b) of the Act and by the regulations of this part, and (iii) be organized and operated in the manner prescribed by section 1301(c) of the Act and by the regulations of this part;

(4) When operational as an HMO, the applicant will enroll, and maintain an enrollment of, the maximum number of members that is available and potential resources will enable it to serve effectively. Maximum number of members is defined as the actual or projected enrollment which the HMO can serve, considering the availability of the required health manpower in the area to be served by the organization and the capacity of the facilities of the organization;

(5) A statement of intent (including evidence of the applicant's ability) to meet the requirements of paragraphs (1) and (2) of section 1301(b) of the Act and the applicable regulations of this part respecting the fixing of payments for basic health services and supplemental health services for which the member has contracted on a prepayment basis under a community rating system; and

(6) In the case of an application for assistance under sections 1304 and 1305 of the Act filed by a nonprofit entity, the applicant will become a nonprofit HMO, will maintain its nonprofit status unless for good cause shown the Secretary releases the applicant from this assurance, and will upon a change in its nonprofit status notify the Secretary immediately.

(c) *Nonmetropolitan areas.* Each application which evidences or projects an enrollment of at least 66 percent from a nonmetropolitan area shall identify the area and indicate the percent of anticipated enrollment to be drawn from that area.

(d) *Medically underserved areas.* Each application which evidences or projects an enrollment of at least 30 percent of its members from a medically underserved population when the HMO first receives financial assistance or becomes operational shall identify the area in which that population resides, the total population of that area, and the percent of anticipated enrollment to be drawn from the medically underserved area. Medically underserved areas are designated by the Secretary taking into consideration at least the following factors:

(1) Ratio of primary care physicians to population;

(2) Infant mortality rate;

(3) Percentage of the population which is age 65 or over; and

(4) Percentage of the population with family income below the poverty level.

The Secretary will designate these areas only after consideration of the comments, if any, of the appropriate health systems agency or State health planning and development agency whose plan covers any part of the area in which the population group resides.[1]

(e) *Health planning agency reviews.* Each applicant must show in its application that it has sent to each health systems agency whose health service area covers any part of the area to be served by the HMO for which the application is submitted (or if there is no such agency, the State health planning and development agency whose State includes any part of the area to be served) a copy of the application concurrent with its submission to the appropriate Regional Office of the Department of Health and Human Services. The agency may then review and comment on the application in accordance with § 110.204.

(f) *Health planning agency approvals.* If applicable State law provides that the application may not be submitted without the approval of the health systems agency, or State health planning and development agency, the applicant shall obtain this approval which must be included as a part of the application.

(g) *Other projects under the Public Health Service Act.* The application shall provide written information describing the applicant's development and operation of any prior projects which were supported by grants or by loans or loan guarantees under Title XIII of the Act. Applicants must also describe projects for the planning or operation of health service delivery programs supported under any other titles of the Public Health Service Act, or for which applications under the Act are currently under consideration.

(h) *Other applications under Title XIII of the Act.* Applicants for more than one grant, loan, or loan guarantee under Title XIII of the Act, simultaneously or over the course of time, are not required to submit duplicate information, but shall indicate where the information was previously contained and shall update appropriate information with each subsequent application. Upon receiving a written request, the HMO shall submit to the appropriate planning agency referred to in paragragph (e) any previous applications for grants, loans, or loan quarantees under Title XIII of the Act not already submitted to that agency.

§ 110.204 What are the standards and procedures for review and comment by the appropriate health systems agency or State health planning and development agency?

(a) *Time, manner, and considerations for review and comment.* If the appropriate health systems agency or State health planning and development agency elects to review and comment upon the application, it shall within 67 days after receiving an application for financial assistance under this part provide to the Secretary, through the appropriate Department of Health and Human Services Regional Office, comments and recommendations regarding the application. Except as provided in paragraph (c) of this section, the agency shall base its review and comment solely on the following considerations:

(1) The needs of enrolled members and reasonably anticipated new members of the HMO or proposed HMO applying for assistance for the health services proposed to be provided by the organization.

(2) The availability of the proposed health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO or proposed HMO applying for assistance. In assessing the availability of health services from these providers, the agency shall consider only whether the services from these providers:

(i) Would be available under a contract of at least five years duration;

(ii) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO or proposed HMO

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[1] A list of medically underserved areas already designated may be obtained by writing the Regional Health Administrator in the appropriate Regional Office of the Department of Health and Human Services at the addresses set forth at 45 CFR 5.31(b).

(for example: Whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);

(iii) Would cost no more than if the services were provided by the HMO or proposed HMO; and

(iv) Would be available in a manner which is administratively feasible to the HMO or proposed HMO.

(b) *Inappropriate considerations for review and comment.*

(1) The health systems agency or State health planning and development agency should not recommend against approval of an application solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, State health plan, or State medical facilities plan.

(2) The health systems agency or State health planning and development agency should not recommend against approval of an application for financial assistance for planning or initial development or initial operating costs under subparts D and E of this part, which is consistent with the basic objectives, time schedules, and plans of an application which it previously approved or recommended for approval.

(c) *Additional considerations for review and comment.* A health systems agency or State health planning and development agency may propose to the Secretary that it be permitted to base its reviews and comments on additional considerations not set forth in paragraph (a) of this section. Any agency making such a request for permission to use additional considerations shall do so in writing, specifying the reasons for the proposal, and shall send a copy of the request to any applicants for financial assistance under this part whose applications are then being reviewed by the agency. No pending reviews may be delayed because the agency has submitted such a request to the Secretary. The Secretary will approve the request if he finds the additional considerations to be consistent with the purpose of Title XIII of the Act. Unless the Secretary has approved the use of the additional considerations, the agency shall base its reviews and comments solely on the considerations set forth in paragraph (a) of this section.

§ 110.205 What additional conditions may the Secretary impose?

(a) The Secretary may, with respect to the approval of any grant, contract, loan, or loan guarantee, impose additional conditions prior to or at the time of any approval when, in his judgment, these conditions are necessary to assure or protect the advancement of the approved project, the interests of public health, or the conservation of project funds.

(b) In approving any application under Section 1303 or 1304 of the Act for feasibility, planning, or initial development, the Secretary may reserve the right to approve the project director.

[44 FR 42076, July 18, 1979. Redesignated and amended at 45 FR 55122, Aug. 18, 1980]

§ 110.206 What confidentiality requirements apply?

(a) Except as set forth in paragraph (b) of this section, each recipient of assistance under this part shall hold confidential all information obtained by its personnel about participants in the project related to their examination, care, and treatment and shall not divulge it without the individual's authorization, unless it is required by law or is necessary to provided service to the individual or in compelling circumstances to protect the health or safety of an individual.

(b) Information may be disclosed in summary, statistical, or other form which does not identify particular individuals. Information may be disclosed, whether or not authorized by the participants, to the Secretary or the Comptroller General if it is necessary for the performance of their duties under the Act. Records pertaining to project participants may be disclosed, whether or not authorized by the participants, to qualified personnel for the purpose of conducting scientific research, but these personnel may not identify, directly or indirectly, any individual participant in any report of the research or otherwise disclose participant identities in any manner.

(c) Separate HHS regulations at 42 CFR Part 2, set forth standards for maintaining the confidentiality of alcohol and drug abuse patient records. Under § 2.12 of the regulations, the applicability of these requirements extends, for example, to all HMOs which have received a loan from the Secretary under Section 1305 of the Act or which have been granted a tax exempt status by the United States Internal Revenue Service. To the extent that an HMO subject to Part 2 would be authorized under paragraph (b) of this section to make a disclosure prohibited by Part 2, the provisions of Part 2 would control.

[44 FR 42076, July 18, 1979. Redesignated at 45 FR 55122 and 55123, Aug. 18, 1980]

§ 110.207 What other HHS regulations apply?

(a) Several other HHS regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure.
45 CFR Part 16—Department grant appeals process.
45 CFR Part 74—Administration of grants.
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effecutation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

(b) Several other HHS regulations apply to loans and loan guarantees under this part. These include, but are not limited to:

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81—Practice and procedure for hearings under Part 80.
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance from HHS.

[45 FR 55123, Aug. 18, 1980]

§ 110.208 For what purposes may grant funds be used?

A grantee may spend funds it receives under this part only according to the approved application and budget, Title XIII of the Act, the terms and conditions of the grant award, the applicable cost principles specified in Subpart Q of 45 CFR part 74, and the regulations of this part.

[45 FR 55123, Aug. 18, 1980]

§ 110.209 What is the effect of a grantee's failure to become or to remain a qualified HMO?

The failure of a grantee to become a qualified HMO in accordance with Subpart F of this part, or to remain a qualified HMO, is a material failure to comply with the terms of the grant. Upon this failure, the subsequent use and disposition of any property acquired with grant funds will be governed by 45 CFR Part 74.

(a) If the grant project period has not yet expired, this failure is grounds for termination of the grant under 45 CFR Part 74.115(a).

(b) If the grant period has expired, property acquired with grant funds will be deemed, under 45 CFR Part 74, Subpart O, to be no longer needed for the program or project for which it was acquired.

[45 FR 55123, Aug. 18, 1980]

§ 110.210 What obligation does the Federal Government have to continue support for an approved project?

(a) The notice of award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. For feasibility grants under Subpart C and planning grants and loan guarantees under Subpart D, this period, called the project period, will usually be for, and cannot exceed, one year. For initial development grants and loan guarantees under Subpart D, the project period will usually be for 1-3 years and cannot exceed three years.

(b) Generally, the initial development grant or loan guarantee will be for one year initially and subsequent continuation awards will also generally be for one year at a time. Although the project period for a feasibility grant and for a planning grant or loan guarantee is limited to one year, the Secretary may either make one additional grant or loan guarantee for such a project or permit additional time (up to one year) for completion of the project. A grantee or a recipient of a loan guarantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the assistance level of such awards will be made after consideration of such factors as the progress and management practices of the grantee or recipient of the loan guarantee, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued assistance is in the best interest of the Federal government.

(c) Neither the approval of any application nor the making of an award commits or obligates the Federal government in any way to make an additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

[45 FR 55123, Aug. 1, 1980]

§ 110.211 What is the effect of a grantee's change from non-profit to for-profit status?

(a) Any non-profit private entity which received a grant under section 1304 of the Act and which becomes a for-profit private entity, shall notify the Secretary of this change of status within 30 days of the change.

(b) Any grantee which becomes a for-profit entity after receiving a grant under section 1304 of the Act shall immediately upon demand by the Secretary repay to the Secretary the total amount of grant funds received under section 1304, unless the Secretary determines for good cause that waiver of all or part of this amount would be in the interest of the United States. This sum constitutes a debt owed by the grantee to the Federal Government, and the Government may recover it from the grantee or its successors or assignees by setoff or other action as provided by law.

[44 FR 42076, July 18, 1979. Redesignated at 45 FR 55123, Aug. 1, 1980, and amended at 47 FR 19340, May 5, 1982]

Subpart C—Grants for Feasibility

Source: 43 FR 6021, Feb. 10, 1978, unless otherwise noted. Surveys

§ 110.301 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart B of this part, are applicable to grants awarded pursuant to section 1303 of the Act for projects to conduct surveys or other activities to determine the feasibility of developing and operating or expanding the operation of health maintenance organizations.

§ 110.302 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit entity which is or proposes to develop or become a health maintenance organization and which received a grant or contract under section 1303 or section 1304 of the Act on or before September 30, 1981, is eligible to apply for an award under this subpart, except that in the case of applications for support of expansion, only organizations which have been found by the Secretary to be qualified health maintenance organizations are eligible to apply.

(b) *Eligible projects.* Awards may be made pursuant to section 1303 of the Act, the regulations of Subpart B of this part, and this subpart, to eligible applicants to assist in conducting surveys or other activities to determine the feasibility of developing or expanding the operation of organizations which meet or propose to meet the requirements under subpart A of these regulations.

[43 FR 6021, Feb. 10, 1978, as amended at 47 FR 19341, May 5, 1982]

§ 110.303 Project elements.

An approvable application must provide:

(a) Statements which describe concisely:

(1) The goals and objectives of the applicant organization and of the proposed health maintenance organization if the proposed health maintenance organization is different from the applicant organization; if it is different, describe the relationship between the two organizations;

(2) The administrative, managerial, and organizational arrangements;

(3) The resources to be used, including consultants whose tasks must be defined adequately to permit an evaluation of the need for such consultants;

(4) The existing or proposed composition of the Board of Directors of the applicant organization and its duties;

(5) The proposed service area and the surrounding community, the number of employed persons and number of primary care physicians located in the proposed service area; and

(6) Intended financial participation of the applicant, specifying the type of contribution, such as cash or services, loan of full- or part-time staff, equipment, space, materials, or other contributions.

(b) In the case of a proposed staff or medical group health maintenance oganization, letters from at least three physicians expressing their interest in the health maintenance organization feasibility study in connection with their eventual participation in the health maintenance organization as providers of basic health services.

(c) In the case of a proposed individual practice association health maintenance organization, letters from the local medical society or societies, or from at least three individual physicians, expressing their interest in the health maintenance organization feasibility study in connection with their eventual participation in the health maintenance organization as providers of basic health services.

(d) Evidence that there is interest in the possible development of a health maintenance organization from one or more employers, or unions, or community leaders in the proposed service area.

(e) Plans for conducting the feasibility study which must include a consolidated time-phased milestone chart indicating proposed funding and manpower to be allocated to each of the six activities below, and a narrative explanation of work plans to accomplish the six activities:

(1) Identification of pertinent State laws, regulations, and practices relating to the intended organizational structure and operation as a health maintenance organization;

(2) Identification of major groups or other potential sources of enrollement to which marketing efforts will be directed, including their existing health plan benefits and payments and the level and scope of major health plan benefits and premiums in the community;

(3) Identification of potential providers and available health manpower necessary to provide basic health services to the number of enrollees projected to be served, and provision of evidence of their willingness to participate in the proposed health maintenance organization;

(4) Development of detailed estimates of expected utilization and the amount to be charged for basic health services when the proposed health maintenance organization becomes operational;

(5) Development of detailed estimates of the enrollment and funds required to reach the financial break-even point. These estimates must take into account all potential sources of income; and

(6) Development of preliminary estimates of the type and number of facilities, if any, necessary to provide health services when the health maintenance organization becomes operational.

(f) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of subpart A of this Part.

(g) In addition, in the case of a qualified health maintenance organization requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organizations has not been operating for five years, such data on a

quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 110.202(c) will be met.

(h) An assurance that the applicant will cooperate with the appropriate health systems agency and State health planning and development agency; and

(i) Written evidence of notification to the local medical society or societies of the applicant's intention to apply for assistance.

§ 110.304 Evaluation and award.

(a) Within the limits of funds available for such purpose, the Secretary may make awards to cover up to 90 percent of the cost of projects, or in the case of projects which will draw not less than 30 percent, not more than the appropriate percentage (as determined under § 110.108(c)), of their anticipated enrollment from medically underserved populations, up to 100 percent of the costs, to those applicants whose projects will, in his judgment, best promote the purposes of section 1303 of the Act and the regulations of this subpart, taking into account:

(1) The appropriateness and completeness with which the applicant addresses the project elements set forth above;

(2) The comments of the appropriate health systems agency or State health planning and development agency;

(3) The degree to which the goals and objectives of the proposed project will promote the purposes of the Act and are consistent with the generally recognized capability of effectively organized and managed health maintenance organizations to reduce inappropriate hospital utilization, to contain health care costs, to use effectively medical and other health manpower, to emphasize early detection and treatment of illness, and to contribute to a better distribution and quality of health care;

(4) Satisfactory evidence of understanding and commitment to the development of a qualified health maintenance organization on the part of the sponsors and the board of directors of the proposed project;

(5) The qualifications of the project director or proposed project director or other person responsible for completion of the feasibility study and a position description adequate to assure that a well-qualified person has been or will be selected;

(6) The thoroughness of the milestone chart and narrative plan for conducting the feasibility study by project staff and any proposed consultants;

(7) The indications of interest obtained from physicians with respect to their eventual participation as providers of basic health services;

(8) The probability of financial viability based on potential sources of financial support for development and operations, on potential sources of enrollment, and on the effect of competing health insurance plans;

(9) The inclusion of medically underserved populations in the projected enrollment;

(10) The location and the number of prepaid health plans already providing health services to a defined population in the applicant's proposed service area and to the extent known the number of organizations already studying health maintenance organization development in the proposed service area;

(11) The level of the applicant's intended contribution to the project;

(12) In the case of an existing prepaid health plan, the potential to become a qualified health maintenance organization;

(13) In the case of expansion projects, the potential rate of increase of expansion, or the potential increase in the area to be served by the expanded health maintenance organization.

(b) In considering applications under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organizations become operational not less than 30 percent of their members will be members of a medically underserved population.

§ 110.305 Funding duration and limitation.

(a) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs: *Provided, however,* That any single grant may not exceed $75,000.

(b) Feasibility survey applicants may propose that the award period be 12 months or less. Feasibility survey projects shall be completed within the period of the award. The Secretary may make not more than one additional grant for a project for a feasibility survey for which a grant has previously been made, and may permit additional time (up to 12 months) for completion of the project if he determines that the additional grant or additional time, or both, is needed to complete the project adequately.

(c) Funds under grants for feasibility surveys shall be used only for activities set forth in § 110.303(e) and for activities designed to fill the gaps referred to in § 110.303(f).

Subpart D—Grants and Loan Guarantees for Planning and Initial Development Costs

SOURCE: 43 FR 6023, Feb. 10, 1978, unless otherwise noted.

§ 110.401 Applicability.

(a) The regulations of this subpart, in addition to the regulations of Subpart B of this part, apply to:

(1) Grants awarded under section 1304 of the Act for projects for the planning and for the initial development of HMOs.

(2) Guarantees made under section 1304 of the Act to non-Federal lenders of payment of the principal of and the interest on loans made for projects for the planning and initial development of HMOs.

(b)(1) Planning projects include projects for (i) the establishment of an HMO, and (ii) the significant expansion (as defined in § 110.202) of the membership or of the area served by an HMO.

(2) Initial development projects include projects for (i) the establishment of an HMO, (ii) the significant expansion (as defined in § 110.202) of the membership or of the area served by an HMO, and (iii) the expansion of the services (as defined in § 110.202) of an HMO.

[45 FR 6059, Jan. 24, 1980]

§ 110.402 Eligible applicants.

Any public entity or nonprofit private entity which is, or which proposes to become, an HMO and which received a grant or contract under section 1303 or section 1304 of the Act on or before September 30, 1981 is eligible to apply for a grant or a loan guarantee under this subpart. A for-profit private entity which is, or which proposes to become, an HMO is only eligible to apply for a loan guarantee under this subpart.

(a) In the case of a for-profit private entity, the applicant must demonstrate that at least 10 percent of the projected membership of the HMO to be established or expanded will be from medically underserved populations.

(b) Only HMOs qualified under Subpart F of this part are eligible to apply for projects for the significant expansion of their membership or of their service areas or for the expansion of their services.

[45 FR 6059, Jan. 24, 1980, as amended at 47 FR 19341, May 5, 1982]

§ 110.403 Project elements for planning.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The goals and objectives of the proposed health maintenance organization;

(2) The administrative, managerial, and organizational arrangements;

(3) The resources to be used including consultants whose tasks must be defined adequately to permit an evaluation of the need for such consultants;

(4) The existing or proposed composition of the Board of Directors of the applicant organization and its duties;

(5) The proposed service area and the surrounding community, the

number of employed persons and number of primary care physicians located in the proposed service area; and

(6) The intended financial participation of the applicant, specifying the type of contribution such as cash or services, loans of full- or part-time staff, equipment, space, materials, facilities, or other contributions.

(b) An assurance that the applicant will cooperate with the appropriate health systems agency and State health planning and development agency.

(c) Written evidence of notification to the local medical society or societies of the applicant's intention to apply for assistance.

(d) Evidence that there is support for the project by organizations, or institutions, or employer groups which may participate in the development of the proposed health maintenance organization.

(e) A detailed report of the results of the activities performed during the feasibility survey or study which established the feasibility of developing the health maintenance organization, as well as of any other activities relating to the development of the health maintenance organization undertaken prior to application for planning assistance. With regard to the report of the feasibility survey, information on the following must be included:

(1) Status of the applicant in terms of pertinent State laws, regulations, and practices relating to operating as a health maintenance organization;

(2) Organizational structure of the proposed health maintenance organization;

(3) The types of population groups which would be sources of prepayment for an operational health maintenance organization and other potential sources of payment for services when operational;

(4) Providers of basic health services who have agreed or might reasonably be expected to agree to provide health benefits;

(5) Sources of payment and operational support including:

(i) Preliminary estimate of the amount to be charged for basic health benefits when the proposed health maintenance organization becomes operational; and

(ii) Estimate of enrollment and income required to reach the financial breakeven point; and

(6) A preliminary estimate of facilities required for operational status.

(f) Concise plans for accomplishing planning stage activities, which must include at a minimum, a description of tasks for each activity listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each such activity (where circumstances indicate that it would be appropriate and consistent with the intent of the Act, additional activities may be proposed):

(1) Recruitment of key project staff which shall include the employment of a full-time project director;

(2) Planning for, and when appropriate, initiation of action relating to compliance with all applicable State requirements, including State certificate of need programs, and with section 1513(e) of the Public Health Service Act;

(3) Development of formal organization;

(4) Establishment and documentation of community support;

(5) Development of a marketing plan which must include the following:

(i) Market assessment:

(A) Precise description of the service area;

(B) Information about prospects for enrollment of groups, including analysis of competing health benefits plans;

(C) Evidence of a willingness on the part of key prospects to offer the health maintenance organization when operational;

(D) An estimate of market potential for a five year period, including a five year enrollment projection.

(ii) Marketing strategy:

(A) Select the major prospects for enrollment;

(B) Develop alternatives to meet the enrollment projections;

(C) Estimate the level and type of marketing effort required to meet the enrollment projection;

(D) Develop a marketing effort and a detailed budget including staffing requirements.

(iii) Marketing materials:

(A) Develop detailed description of specifications for marketing and enrollment literature;

(B) Develop prototype membership materials including membership cards, subscriber agreements, handbooks and certificates, health questionnaires, etc.

(6) Definition of the health services and options, if any to be offered;

(7) Identification of providers of basic health services needed to provide those services to the projected enrollment, and drafting of proposed agreements to negotiate with these providers;

(8) Planning for necessary facilities and equipment and their financing;

(9) Development of premium structure;

(10) Development of budget and financial plan, including alternative plans if enrollment varies significantly from projections;

(11) Obtaining of required health systems agency or agencies and State health planning and development agency determinations; and

(12) Establishment of the individual practice association entity if appropriate to the intended organizational structure when operational as a health maintenance organization.

(g) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of Subpart A of this part.

(h) In addition, in the case of a qualified health maintenance organization requesting assistance for significant expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed significant expansion which demonstrate that the definition of significant expansion in § 110.202(c) will be met.

§ 110.404 Project elements for initial development.

An approvable application must provide:

(a) Written evidence satisfactory to the Secretary that the feasibility of the establishment and operation or expansion has been established by the applicant and that sufficient planning for the establishment or expansion has been conducted by the applicant. In addition, applicants must provide the information, assurances and evidence required by § 110.403 (a), (b), (c), (d), and (e), and must report all other activities relating to the development of the health maintenance organization undertaken prior to application for initial development assistance.

(b) Detailed plans, which must include, at a minimum, tasks designed to accomplish the activities listed below, accompanied by a time-phased milestone chart indicating proposed funding and manpower to be allocated to each (where circumstances indicate that it would be appropriate and consistent with the intent of the Act, additional activities may be proposed in the application):

(1) Development of a schedule to meet the requirements of Subpart A of this part;

(2) Completion of activities related to resolution of legal issues;

(3) Recruitment and training of personnel essential for operation as a health maintenance organization;

(4) Development of a comprehensive financial plan;

(5) Organization of physician health services;

(6) Organization of other basic health services;

(7) Development of a schedule to construct, lease, renovate or otherwise obtain health maintenance organization facilities;

(8) Organization of ambulatory care facility;

(9) Implementation of a staffing plan that demonstrates compliance with the appropriate 15 or 30 percent limitation on contracts for basic and supplemental health services (see

§ 110.104(a)), and formalization of contract arrangements;

(10) Further refinement of the projected market to be served by obtaining specific evidence of employer or union willingness to offer the health maintenance organization option on specific dates;

(11) Initiation of enrollment plan; and

(12) Establishment of any working capital or reserves or both as may be required by State authorities.

(c) Evidence from physicians and from one or more hospitals indicating that they intend to become providers of basic health services for the proposed health maintenance organization:

(1) In the case of an individual practice association-type health maintenance organization, there must be such evidence from a number of physicians adequate to serve the proposed enrollment; and

(2) In the case of a non-individual practice association-type health maintenance organization, there must be such evidence from at least three physicians, indicating that they are willing to be employed by or to contract with the proposed health maintenance organization.

(d) In the case of an applicant which intends to serve Title XIX eligibles or Title XVIII beneficiaries as a part of the planned enrollment, as appropriate:

(1) Evidence that the State Title XIX agency is willing to negotiate a prepaid capitation contract in the form of a letter or other document from the State Title XIX agency; or

(2) Evidence that the applicant is planning to or has entered into a contract under Title XVIII as a health maintenance organization.

(e) In addition, in the case of an operational prepaid health plan which proposes to become a qualified health maintenance organization, an identification of gaps between its current operation and the requirements of Subpart A of this part.

(f) In addition, in the case of qualified health maintenance organizations requesting assistance for expansion:

(1) Data on prepaid membership totals for annual intervals over the past five years, or if the health maintenance organization has not been operating for five years, such data on a quarterly basis for the time during which it has been in operation;

(2) A description of the current health service delivery facilities, including an estimate of their capacity;

(3) The number and specialties of current health professionals serving its members; and

(4) The plans for the proposed expansion which demonstrate that the definition of "expansion of services" or of "significant expansion" of membership or service area in § 110.202 will be met.

[43 FR 6023, Feb. 10, 1978, as amended at 45 FR 6059, Jan. 24, 1980]

§ 110.405 Funding duration and limitation.

(a) *Planning projects.* (1) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for project costs: *Provided,* That any single grant and the amount of principal of any single loan guaranteed under section 1304 of the Act may not exceed $200,000.

(2) In considering applications for grants for planning projects under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for planning projects under this subpart, the Secretary will give special consideration to applications for projects for health maintenance organizations which will have at least 10 percent of their projected membership from medically underserved populations. Applicants may propose that the award period be for one year or less, as appropriate to the planning activities to be accomplished. Planning projects shall be completed within the period of the award. The Secretary may not make more than one additional grant or loan guarantee for a planning project for which a grant or loan guarantee has previously

been made, and may permit additional time (up to 12 months) for completion of the project if he determines that the additional grant or loan guarantee (as the case may be) or additional time, or both, is needed to complete the project adequately.

(3) Funds under grants and loans guaranteed for planning projects shall be used only for the activities set forth in § 110.403(f) and for activities required to fill the gaps referred to in § 110.403(g).

(b) *Initial development projects.* (1) The aggregate amount of loan guarantees and grants for any initial development project may not exceed the amount specified by section 1304(f)(2) of the Act. The cumulative total of grants made to and the principal of loans guaranteed for an HMO for initial development projects may not exceed the amount specified by section 1304(f)(3) of the Act.

(2) A grant may only be made for initial development costs incurred in a period not to exceed three years.

(3) In considering applications for grants for initial development projects under this subpart, the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organization becomes operational, not less than 30 percent of its members will be members of a medically underserved population. In considering applications for loan guarantees for initial development projects under this subpart, the Secretary will give special consideration to applications for projects for health maintenance organizations which will have at least 10 percent of their projected membership from medically underserved populations.

(4) Funds under grants and loans guaranteed for projects for initial development shall be used only for activities set forth in § 110.404(b) (except that such funds may not be used for the costs of construction or for recruitment of personnel who will not engage in practice principally for the health maintenance organization) and for activities required to fill gaps referred to in § 110.404(e).

[43 FR 6023, Feb. 10, 1978, as amended at 45 FR 6059, Jan. 24, 1980]

§ 110.406 Evaluation and award.

(a) Within the limits of funds available for such purpose, the Secretary may make awards to cover up to 90 percent of the cost of projects, or in the case of projects which will draw not less than 30 percent nor more than the appropriate percentage (as determined under § 110.108(c)) of its anticipated enrollment from medically underserved populations, up to 100 percent of the costs, to those applicants whose projects will, in his judgment, best promote the purposes of section 1304 of the Act and the regulations of this subpart, taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in § 110.403 or § 110.404.

(2) The comments of the appropriate health systems agency or State health planning and development agency.

(3) Whether the feasibility of the project has been established, and in the case of initial development applications, whether all required planning activities have been accomplished.

(4) The appropriateness of the goals and objectives of the proposed project.

(5) The effectiveness the proposed organization may reasonably be expected to have in reducing inappropriate hospital utilization, containing health care costs, using medical and other health manpower, emphasizing early detection and treatment of illnesses, and achieving a better distribution and quality of care.

(6) The capability of the applicant to organize and manage the project successfully.

(7) Evidence of the applicant's intended contribution to the project.

(8) Evidence by letters or similar statements of intent from providers expressing a willineness to be employed by or contract with the proposed health maintenance organization for the provision of basic health services and evidence that providers as necessary, will contract with the health maintenance organization other than as members of its staff or through medical groups or individual practice associations.

(9) Evidence, in form of letters, from individuals, groups, or organizations indicating that they support the development and operation of the proposed health maintenance organization.

(10) The results of the Secretary's assessment of marketing capability and the prospects for eventual financial viability as an operational health maintenance organization without continued Federal support.

(11) The inclusion of medically underserved populations in groups to be enrolled.

(12) Location relative to the number of organizations providing health services to a defined population on a prepaid capitation basis, which are already operating in the area.

(13) The percentage of anticipated total enrollment to be drawn from nonmetropolitan areas to be served.

(14) In the case of an existing organization operating on a prepaid capitation basis, the applicant's potential for expeditious transition into a qualified health maintenance organization.

(15) In the case of expansion projects, the potential rate of increase of expansion, or the potential increase in the area to be served by the expanded health maintenance organization.

(b) In considering applications under this subpart the Secretary will give priority to applications which contain assurances satisfactory to the Secretary that when the organizations become operational, not less than 30 percent of their members will be members of a medically underserved population.

§ 110.407 Loan guarantee provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan guaranteed by the Secretary under this subpart shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan guarantee by the Secretary. The Secretary may however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan and approved by the Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interests, to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment may be deferred, with payment of interest only by the applicant during a period to be specified in an agreement between the applicant and the Secretary. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[43 FR 6023, Feb. 10, 1978, as amended at 47 FR 19341, May 5, 1982]

Subpart E—Loans and Loan Guarantees for Initial Costs of Operation

SOURCE: 43 FR 6026, Feb. 10, 1978, unless otherwise noted.

§ 110.501 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart B, of this part are applicable to loans and loan guarantees awarded pursuant to section 1305 of the Act.

§ 110.502 Definitions.

(a) "Costs of operation" means any cost incurred in the first 60 months of operation or expansion which:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted

by State regulatory authority is not a capital cost;

(2) Is required by State regulatory authority to meet reserved or tangible net equity requirements;

(3) Is for a payment made to reduce balance sheet liabilities existing at the beginning of the 60 month period, but only if (i) the payment has been approved in writing by the Secretary, and (ii) the total of these payments does not exceed 20 percent of the amount of the loan; or

(4) Is for a small capital expenditure, but only if (i) the cost has been approved in writing by the Secretary, and (ii) the total of these costs does not exceed $200,000 in any 12 month period and $400,000 during the first 60 months of operation or expansion.

(b) "First 60 months of operation or expansion" means the 60-month period beginning on the first day of the month during which the health maintenance organization first provides services to members, or in the case of significant expansion, first provides services in accordance with its expansion plan.

(c) "Any twelve month period" means the twelve month period beginning on the first day of any month.

(d) "Small capital expenditures" means expenditures for (1) equipment (as defined in 45 CFR 74.132); and (2) alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603, Feb. 22, 1979; 45 FR 6060 Jan. 24, 1980]

§ 110.503 Eligibility.

(a) *Eligible applicants.* (1) Any public qualified health maintenance organization is eligible to apply for a loan under this subpart.

(2) Any private qualified health maintenance organization is eligible to apply for a loan or a loan guarantee under this subpart.

(b) *Eligible projects*—(1) *Loans.* In the case of public or private qualified health maintenance organizations, loans may be made pursuant to section 1305 of the Act and the regulations of Subpart B of this part and this subpart to eligible applicants to assist them in meeting the amount by which their costs of operation during a period not to exceed the first 60 months of their operation exceed their revenues in such period, or in meeting the amount by which their costs of operation which the Secretary determines are attributable to significant expansion in their membership or area served, as defined in § 110.202(c), and which are incurred during a period not to exceed the first 60 months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion.

(2) *Loan guarantees.* Loan guarantees may be made pursuant to section 1305 of the Act, and the regulations of Subpart B of this part and this subpart, to guarantee to non-Federal lenders payment of the principal of and the interest on loans made to any private qualified HMO for the amounts referred to in paragraph (b)(1) of this section.

[43 FR 6026, Feb.10, 1978, as amended at 45 FR 6060, Jan. 24, 1980; 47 FR 19341, May 5, 1982]

§ 110.504 Project elements.

An approvable application must provide:

(a) Statements which describe in detail:

(1) The applicant's adequate accomplishment of feasibility survey, planning, and development activities; and

(2) The health maintenance organization's management capability.

(b) Detailed information on the health maintenance organization's marketing plan and enrollment forecasts and experience.

(c) A detailed narrative statement describing:

(1) All existing and planned provider arrangements including copies of all executed contracts; and

(2) All facilities to be used in the delivery of health services.

(d) Financial information in such detail as the Secretary may prescribe.

(e) Evidence that any certificate of need required under State law for the operation of the health maintenance organization has been obtained by the applicant.

§ 110.505 Reserve requirement.

The applicant receiving a loan or loan guarantee under section 1305 of the Act shall establish a restricted reserve account beginning at the point when the revenues and costs of operation of the health maintenance organization reach the break-even point, or by the end of the 60 month period following the making of the loan or the guarantee under section 1305 of the Act, whichever is sooner, unless a longer period is approved by the Secretary. This reserve shall be so constituted as to accumulate no later than twelve (12) years following the endorsement of the loan or loan guarantee, an aggregate amount equal to one year's principal of and interest on the loan, as determined under the terms of the loan made or guaranteed.

[43 FR 6026, Feb. 10, 1978, as amended at 45 FR 6060, Jan. 24, 1980]

§ 110.506 Evaluation and award.

Within the limits of funds available for such purposes, the Secretary may award loans or loan guarantees to those applicants whose projects will, in his judgment, best promote the purposes of section 1305 of the Act and the regulations of this part, taking into account:

(a) The ability of the health maintenance organization to achieve financial viability;

(b) The ability of the health maintenance organization to make repayments of the principal and interest when due and to have additional funds to defray the remaining operating deficits;

(c) The comments, if any, of the appropriate health systems agency or State health planning and development agency;

(d) The relative distribution of qualified applicants with respect to the following factors:

(1) The inclusion of medically underserved populations in the groups to be enrolled;

(2) Location relative to the number of organizations providing health services to a defined population on a prepaid capitation basis, which are already operating in the proposed area; and

(3) The percentage of anticipated total enrollment drawn from nonmetropolitan areas served or to be served by the applicant.

§ 110.507 Funding duration and limitation.

(a) The aggregate amount of principal of loans made to an HMO, or guaranteed for an HMO, or both, under section 1305 of the Act, shall not exceed the applicable maximum amounts provided in section 1305. In any twelve month period, the amount disbursed to an HMO under section 1305 of the Act (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under section 1305 of the Act) may not exceed the maximum amounts provided in section 1305.

(b) The approval of any loan or loan guarantee shall not obligate the United States in any way to make any additional loan or loan guarantee with respect to the approved application or portion thereof, except as may be otherwise set forth in the agreement between the United States and the approved applicant.

(c) In considering applications for loan guarantees under section 1305 of the Act and this subpart, the Secretary will give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

(Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e—300e-17))

[43 FR 6026, Feb. 10, 1978, as amended at 44 FR 10603, Feb. 22, 1979; 47 FR 19341, May 5, 1982]

§ 110.508 Loan provisions.

(a) *Disbursement of loan proceeds.* The principal amount of any loan made or guaranteed by the Secretary under this subpart shall be disbursed to the applicant in accordance with an agreement to be entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary may, however, approve a shorter repayment period where he determines that a repayment period of less than 22 years is more appropriate to an applicant's total financial plan.

(c) *Repayment.* The principal amount of each loan or loan guarantee, together with interest thereon, shall be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan or loan guarantee and approved by the Secretary prior to or at the time of his endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary shall be repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation may be deferred, with payment of interest only by the applicant during such period. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[43 FR 6026, Feb. 10, 1978, as amended at 47 FR 19341, May 5, 1982]

Subpart F—Qualification of Health Maintenance Organizations

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318 of the Public Health Service Act, as amended, 95 Stat. 572-578 (42 U.S.C. 300e-300e17).

SOURCE: 47 FR 31667, July 21, 1982, unless otherwise noted.

§ 110.601 Applicability.

The regulations of this subpart apply to any entity seeking a determination by the Secretary under section 1310(d) of the Act that it is a qualified health maintenance organization (HMO).

§ 110.602 Definitions.

In addition to the terms defined in § 110.101 of this part, as used in this subpart:

"Operational qualified "HMO" means an HMO which the Secretary has determined provides basic and supplemental health services to all of its members in accordance with Subpart A of this part and is organized and operated in accordance with Subpart A of this part.

"Preoperational qualified HMO" means an entity which the Secretary has determined will, when it becomes operational, be a qualified HMO.

"Transitionally qualified HMO" means an entity which operates a prepaid health care delivery system and which the Secretary has determined meets the requirements of § 110.603(b). A transitionally qualified HMO is considered a "qualified HMO" for the purpose of compliance by an employer with the requirements of section 1310 of the Act and Subpart H of this part. Under these requirements, the employer must include the HMO in its health benefits plan so long as the HMO's qualification has not been revoked under section 1312(b) of the Act and § 110.904(d) of this part.

§ 110.603 Requirements for qualification.

Upon the basis of an application submitted in accordance with this subpart and any additional information and investigation (including site visits) that the Secretary may require:

(a) The Secretary will determine that the applicant is an operational qualified HMO upon finding that it meets the requirements of Subpart A of this part and if it provides written assurances satisfactory to the Secretary, within 30 days of the date of the Secretary's determination, that it:

(1) Provides and will provide basic health services (and any contracted for supplemental health services) to its members;

(2) Provides and will provide these services in the manner prescribed by section 1301(b) of the Act and Subpart A of this part;

(3) Is organized and operated, and will continue to be organized and operated, in the manner prescribed by section 1301(c) of the Act and Subpart A of this part;

(4) Under arrangements which will safeguard the confidentiality of patient information and records, will provide access to the Secretary and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operations as an HMO, and to any facilities operated by the entity; and

(5) Will continue to comply with any other assurances which the entity has given to the Secretary under §§ 110.203(b), 110.303(h), and 110.403(b).

(b) The Secretary may determine that an applicant is a transitionally qualified HMO upon finding that it currently is organized and is providing prepaid health services as described in this paragraph and if it provides written assurances satisfactory to the Secretary, within 30 days of the date of the Secretary's determination, that it will:

(1) With respect to all new group and individual (non-group) contracts which it enters into after the date of the Secretary's determination, provide basic health services (and any contracted for supplemental health services) to members enrolled under these contracts and will provide these services in the manner prescribed by Subpart A of this part, and with respect to these members, will be organized and operated in accordance with § 110.108 of this part.

(2) With respect to its group and individual contracts which are in effect on the date of the Secretary's determination and which are renewed or renegotiated during the period approved by the Secretary under paragraph (b)(2)(iii) of this section in accordance with the plan so approved:

(i) Provide at least those services specified in the following sections of this part (except that these services may be limited as to time and cost): § 110.102(a)(1) (physician services); § 110.102(a)(2) (outpatient services and inpatient hospital services); § 110.102(a)(3) (medically necessary emergency health services); and § 110.102(a)(6) (diagnostic laboratory and diagnostic and therapeutic radiologic services);

(ii) Be organized and operated in accordance with § 110.108 (except that it need not assume full financial risk for the provision of basic health services as required by § 110.108(b), and need not abide by the limitations on insurance of § 110.108(b)(1) and (3)) and provide that payment for basic health services shall be in accordance with § 110.105 (except that it need not comply with (A) the requirement for a community rating system of § 110.105(a)(3), (B) the limitations on copayments of § 110.105(a)(4), and (C) the requirement of § 110.106(b) that supplemental health services payments which are fixed on a prepayment basis be fixed under a community rating system);

(iii) Implement a time-phased plan acceptable to the Secretary which specifies definite steps for meeting, at the time of renewal of each group or individual contract, but not to exceed 3 years from the date of the Secretary's determination, all the requirements of Subpart A of this part; and

(iv) Upon completion of the time-phased plan, (A) provide basic and supplemental health services to all of its members, (B) provide these services to all of its members in the manner prescribed by Subpart A of this part, and (C) be organized and operate in the manner prescribed by Subpart A of this part.

(c) The Secretary may determine that an applicant is a preoperational qualified HMO if it provides, within 30 days of the Secretary's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of Subpart A of this part. Upon notification by the applicant to the Secretary that it has become operational, the Secretary will, within 30 days of this notification, make a determination whether the applicant is an operational qualified HMO. In the absence of this determination, the organization is not an operational qualified HMO even though it becomes operational.

(d) If the Secretary determines that an applicant meets the requirements for qualification and the applicant fails to sign its assurances within 30 days following the date of the determination, then the Secretary will notify the applicant in writing that its application is considered withdrawn and that is not a qualified HMO.

(e) An HMO which has more than one regional component, as described in § 110.105(b)(3)(iii), will be considered qualified for those regional components for which assurances have been signed in accordance with this section.

[47 FR 31667, July 21, 1982; 47 FR 35194, Aug. 13, 1982]

§ 110.604 Application requirements.

An applicant seeking a determination that it is a qualified HMO under this subpart shall apply to the Secretary in the form and manner which the Secretary prescribes.[1] The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute and the regulations of this part. The applicant must provide a complete description of how the applicant meets or will meet the requirements of Subpart A of this part and applicable sections of the Act.[2] An applicant receiving a denial may not submit a new application for qualification until at least four months after the date of this notice of that determination.

[47 FR 31667, July 21, 1982; 47 FR 35194, Aug. 13, 1982]

§ 110.605 Evaluation and determination of qualification.

(a) The Secretary will evaluate applications submitted under this subpart and will obtain any additional necessary information, employing site visits, public hearings or any other appropriate procedures. If an application is incomplete, the Secretary will notify the applicant and provide it with an opportunity to furnish the missing information within 60 days of the date of the notice. Following the evaluation of all relevant information, the Secretary will determine whether the applicant meets the appropriate requirements of §§ 110.603 and 110.604, section 1301 of the Act, and Subpart A of this part.

(b) Upon finding that an applicant (1) does not appear to meet the requirements for qualification and (2) appears to be able to meet the requirements within 60 days, the Secretary will issue to the applicant a notice of intent to deny qualification and a summary of the basis for this preliminary finding. Within 60 days of the date of this notice, the applicant may respond in writing to the issues or other matters which were the basis for the Secretary's preliminary finding, and may revise its application to remedy any defects identified by the Secretary.

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[1] Application forms and instruction may be obtained by writing the Office of Health Maintenance Organizations, Division of Qualification, Park Building—3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857.

[2] Applicants should be aware that provisions of the Freedom of Information Act, 5 U.S.C. 552, may require disclosure of certain official Government records. Regulations of the Department of Health and Human Services, 45 CFR Part 5, provide exceptions to disclosure. Applicants submitting material which they feel is covered by these exceptions should label the material "privileged" and include a concise explanation of the applicability of 45 CFR Part 5. Upon receipt of a request for information under the Freedom of Information Act, the Secretary will examine the information and determine whether it is subject to disclosure. As part of this determination, the Secretary will decide whether information may not be disclosed under 18 U.S.C. 1905. Under this statute, the Department may not disclose any information not authorized by law that relates to certain confidential information such as trade secrets, processes and confidential financial information.

(c) The Secretary will notify each applicant for qualification under this subpart of the determination and the basis for the determination.

(d) Upon the denial of an application for qualification under this subpart, the Secretary will notify the applicant in writing and provide the applicant an opportunity to request a reconsideration of the determination. A request for reconsideration must be submitted in writing, within 60 days following the date of the notification of denial, be addressed to the officer or employee of the Department of Health and Human Services who has denied the application, and set forth the grounds upon which the reconsideration is requested, specifying the material issues of fact and of law upon which the applicant relies. Reconsideration will be based upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to the Secretary. The Secretary will rovide written jotice of the reconsidered determination to the applicant. The jotice will sat forth the basis for the determination.

(e) The Secretary will publish on a monthly basis in the FEDERAL REGISTER the names, addresses, and descriptions of the service areas of the newly qualified HMOs. A cumulative list of qualified HMOs may be obtained by writing the Document Control Unit, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, or by visiting that Office between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Interested persons should contact that Office between 8:00 a.m. and 4:30 p.m., Monday through Friday, to make an appointment to obtain additional information regarding qualified HMOs.

[47 FR 31667, July 21, 1982; 47 FR 35194, Aug. 13, 1982]

Subpart G—[Reserved]

Subpart H—Employees' Health Benefits Plans

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17)

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted.

§ 110.801 Definitions.

In addition to the terms defined in §§ 110.101 and 110.602, as used in this subpart:

"Bargaining representative" means a representative designated or selected for the purposes of collective bargaining under the National Labor Relations Act, as amended, (29 U.S.C. 151 *et seq.*) or under the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or under a public entity collective bargaining agreement, or under the laws of any State or political subdivison thereof, or other employee representative designated or selected under any law.

"Carrier" means a voluntary association, corporation, partnership, or other organization which is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

"Collective bargaining agreement" means an agreement entered into between an employing entity and the bargaining representative of its employees, and includes agreements entered into on behalf of groups of employing entities with the bargaining representative of their employees in accordance with the provisions of the National Labor Relations Act, as amended (29 U.S.C. 151 *et seq.*), or the Railway Labor Act, as amended, (45 U.S.C. 151 *et seq.*) or the laws of any State or political subdivision thereof.

"Designee" means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of membership in a qualified health maintenance organization to their eligible employees.

"Eligible employee" means an employee who is eligible to participate in a health benefits plan.

"Employee" means any individual employed by an employer or public entity on a full- or part-time basis.

"Employer" shall have the meaning given that term in Section 3(d) of the Fair Labor Standards Act of 1938, as amended, (29 U.S.C 203(d), 203(x)), except that the term "employer" includes non-appropriated fund instrumentalities of the Government of the United States, but does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Rate Commission) of any of the foregoing; or (2) a church, convention or association of churches, or any organization operated, supervised, or controlled by a church, convention, or association of churches which organization (i) is an organization described in section 501(c)(3) of the Internal Revenue Code of 1954, and (ii) does not discriminate (A) in the employment, compensation, promotion, or termination of employment of any personnel, or (B) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through an HMO.

"Employing entity" means an employer or public entity.

"Employing entity-employee contract" means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

"Group enrollment period" means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

"Health benefits" means health benefits and services.

"Health benefits contract" means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

"Health benefits plan" means any arrangement for the provision of, or payment for, any of the basic and supplemental health benefits described in §§ 110.102 and 110.103 of this Part offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

"Public entity" means a State as defined by section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)), a political subdivision of a State, or any agency or instrumentality of the foregoing. "Political subdivision" includes counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

"To offer a health benefits plan" means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents, and to make a financial contribution to the plan whether the financial contribution by the employing entity on behalf of these employees is made directly or indirectly, (e.g. through payments on any basis into a health and welfare trust fund).

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982]

§ 110.802 Applicability.

The regulations of this subpart apply in each calendar year to:

(a) Each employer which was required during any calendar quarter of the previous calendar year to pay its employees the minimum wage specified by Section 6 of the Fair Labor Standards Act of 1938 (or would have been required to pay its employees the minimum wage but for Section 13(a) of that Act) and which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees; and

(b) Each public entity, as a condition of the payment to the State of funds under Sections 314(d), 317, 318, 1002, 1525, or 1610 of the Public Health Service Act, which during any calendar quarter of the previous calendar year employed an average of not less than 25 employees, if the employer or public entity:

(1) Offers, or if there is offered on behalf of the employer or public entity, in the calendar year beginning after any calendar quarter of the previous calendar year in which the employer or public entity employed an average of not less than 25 employees, a health benefits plan to its eligible employees; and

(2) Has received a written request for inclusion in the employer's or public entity's health benefits plan (which request meets the requirements of § 110.803) from one or more qualified HMOs which provide basic health services in an HMO service area in which at least 25 employees of the employer or the public entity, respectively, reside.

§ 110.803 Requirements for a request for inclusion of the HMO option in a health benefits plan; employing entity response.

(a) *Time limitations.* (1) Unless otherwise agreed to by the HMO and the employing entity or designee, an HMO's request for inclusion in an employing entity's health benefits plan must be received by the employing entity or designee no more than 365 days and not less than 180 days before the expiration or renewal date of a health benefits contract or employing entity-employee contract, and no more than 365 days and not less than 180 days before the expiration date of a collective bargaining agreement, or in the case of a public entity, such longer period as may be prescribed by State law.

(2) For the purposes of this paragraph:

(i) A collective bargaining agreement that is automatically renewable or without fixed term shall be treated as having an expiration or renewal date on the earliest anniversary date of the collective bargaining agreement.

(ii) A collective bargaining agreement that is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement shall be treated as having an expiration or renewal date at the time provided by the agreement for discussion of these changes.

(b) *To whom the written request is to be directed.* The request for inclusion must be in writing and (1) in the case of an employer, be directed specifically to the employer's managing official at the employer site being solicited or to the employer's designee; and (2) in the case of a public entity, be directed to the Chief Executive Officer of the public entity, or to the public entity's designee.

(c) *Information which the request must include.* The request must (1) Provide evidence that the Secretary has determined that the HMO is a qualified HMO in accordance with section 1310(d) of the Act and Subpart F of this part;

(2) Describe the HMO's service area or proposed service area and give the dates basic and supplemental health services will be provided in the area or areas;

(3) Indicate whether the services of health professionals which are provided as basic health services are provided through health professionals who are (i) members of the staff of the organization, or (ii) members of a medical group(s), or (iii) members of an individual practice association(s), or (iv) health professionals who have contracted with the HMO for the provision of these services or (v) any combination of the above;

(4) If the HMO provides health services through an individual practice association(s), provide a listing of member physicians by name, specialty, and whether they are accepting new patients from the HMO membership. This listing must be current within 90 days of the date of the request for inclusion;

(5) If the HMO provides health services other than through an individual practice association, provide for each ambulatory care facility the facility's address, days and hours of operation, a statement whether it is accepting new patients from the HMO membership, and the names and specialities of the facility's providers of basic and supplemental health services. This information must be current within 90 days of the date of the request for inclusion;

(6) List the hospitals where HMO members will be provided basic and supplemental health services;

(7) Identify (i) the nature of the HMO entity, i.e., for profit or nonprofit, public or private, sole proprietorship, partnership, or stock or nonstock corporation, , (ii) the members of the HMO's policymaking body, and (iii) the principal managing officer of the HMO;

(8) Provide a statement of the HMO's capacity to enroll new members and the likelihood of any future limitations on enrollment;

(9) Provide the HMO's most recently audited annual financial statements;

(10) Provide proposed implementing agreements between the HMO and the employer, public entity, or designee for the HMO offering;

(11) Provide sample copies of solicitation brochures and membership literature which will be used in the offer of the HMO alternative to employees;

(12) State either (i) the HMO's current rates, including copayments, if any, for basic (and uniformly included supplemental) health services and the dates these rates became effective, or (ii) the HMO's estimated rates for these services.

(d) *Employing entity response.* An employing entity or designee shall respond in writing to an HMO's request for inclusion no later than 60 days after the receipt of the request and shall state whether the employing entity has 25 or more employees who reside within the service area of the HMO. If so, the employing entity or designee shall also state the expiration or renewal dates of its health benefits contracts, employer-employee contracts, and public entity-employee contracts covering these employees, the amount of the employing entity's current contribution (and, where applicable, the employee's contribution) for health benefits, including the dates those contribution levels became effective, and the expiration dates of any collective bargaining agreements covering these employees. In addition, in this response, a public entity or its designee shall furnish the HMO with a description of health benefits, including limitations and exclusions, required under State law or regulation for health benefits plans for employees of the public entity.

(e) *Effect of inadequate request.* If the request for inclusion does not meet the requirements of paragraphs (a) through (c) of this section, the employing entity is not required to include the HMO alternative in its employees' health benefits plan under § 110.805 until the HMO makes its request in accordance with those paragraphs. In such a case, the employing entity or its designee shall, within 60 days after receipt of the request, notify the HMO in writing of the basis for its conclusion that the request does not meet the requirements of paragraphs (a) through (c) of this section.

(f) *New request for inclusion.* If an employing entity includes the HMO alternative in a health benefits plan in accordance with a request meeting the requirements of paragraphs (a) through (c) of this section, the employing entity shall offer the HMO alternative to the employees described in § 110.806(e)(2) during the entire health benefits year. However, if no employees enroll during the health benefits year, the HMO seeking inclusion in the health benefits plan for subsequent enrollment periods shall submit a new request in accordance with paragraphs (a) through (c) of this section.

(g) *Discretionary offering of HMO alternative.* Nothing in this subpart prevents the employing entity or designee from offering the HMO alternative at any time by mutual agreement with the HMO.

§ 110.804 Offer of HMO option to employees.

(a) *Inclusion of HMO option.* An employing entity subject to § 110.802 shall, at the time a health benefits plan is offered to its eligible employees, include in the plan the option of membership in qualified HMOs in accordance with this section.

(b) *Employees to whom the HMO option must be offered.* Each employing entity subject to this subpart shall offer the option of membership in a qualified HMO to each eligible employee, or to each eligible employee and his or her eligible dependents, who reside within the service area of the qualified HMO being offered.

(c) *Manner of offering the HMO option.* (1) For the employees of an employing entity subject to this subpart who are represented by a bargaining representative, the offer of membership in a qualified HMO (i) must first be made to the bargaining representative, and (ii) if the offer is accepted by the representative, must then be made to each represented employee.

(2) For those employees not represented by a bargaining representative, the offer must be made directly to those employees in accordance with this subpart.

§ 110.805 HMOs which must be included in a health benefits plan.

(a) *HMOs providing basic health services through varying arrangements with health professionals.* If more than one qualifed HMO engaged in the provision of basic health services in an area in which eligible employees of an employing entity subject to this subpart reside has requested inclusion in the employer's or public entity's health benefits plan as provided by § 110.802(a)(2)(ii), and if:

(1) One or more of these organizations provides more than one-half of its basic health services through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups), and

(2) One or more of these organizations provides its basic health services which are provided by physicians through (i) an individual practice association (or associations), or (ii) a combination of such an association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization, then, of the qualified HMOs included under this section in a health benefits plan of an employing entity subject to this subpart, at least one shall be an organization which provides basic health services as described in paragraph (a)(1) of this section and at least one shall be an organization which provides basic health services as described in paragraph (a)(2) of this section. For purposes of this paragraph, individual physicians and other health professionals who have contracted with the HMO do not include health professionals who are members of the HMO's staff, of medical groups, or of entities which would be medical groups but for the requirements of paragraph (3)(i) of the definition of medical group in § 110.101.[1]

(b) *Additional HMOs which must be included.* An employing entity subject to this subpart shall offer the option of membership in additional qualified HMOs to its eligible employees, described in paragraphs (b)(1) and (2) of this section, if the additional qualified HMOs demonstrate that their service areas include the place of residence of at least 25 employees of the employing entity:

(1) Who do not reside in the service area of qualified HMOs already included in the employing entity's health benefits plan; or

(2) To whom membership in qualified HMOs already included in the health benefits plan is not available because these HMOs have closed their enrollment of additional eligible employees of the employing entity.

(c) *Alternate HMOs which may be included.* An employing entity subject to this subpart is not required to include in the health benefits plan offered to eligible employees the option of membership in the specific qualified HMO which initiated the request for inclusion in the health benefits plan if (1) the employing entity or designee includes in the health benefits plan the option of membership in one or more other qualified HMOs that may not have made a request within the time limit of § 110.803(a) but are willing to be included, (2) these latter HMOs are of the same type (i.e., as described in paragraph (a)(1) or (2) of this section) as the HMO which submitted the timely request, and (3) all of the employees of the employing entity residing in the service area of the HMO submitting the timely request reside in areas served by these latter HMOs.

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[1] These requirements are that the members of the medical group "as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to members of an HMO."

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982]

§ 110.806 How the HMO option is to be included in the health benefits plan.

(a) *HMO access to employees.* The employing entity shall provide each qualified HMO which is included in its health benefits plan with fair and reasonable access, not less than 30 days prior to and during the group enrollment period, to employees referred to in § 110.804(b) for purposes of presenting and explaining its program in accordance with § 110.108(c) of this part. This access shall include, at a minimum, the opportunity for the distribution of educational literature, brochures, announcements of meetings, and other relevant printed materials meeting the requirement of § 110.108(c) to each employee referred to in § 110.804(b). In no event shall the employing entity provide qualified HMOs access to eligible employees which is more restrictive or less favorable than the access it provides other offerors of alternatives included in the health benefits plan, whether or not these offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* The HMO shall give the employing entity or designee the opportunity to review, revise, and approve HMO educational and offering materials before distribution. Revisions shall be limited to correcting factual errors and misleading or ambiguous statements, unless otherwise agreed to by the HMO and the employer or public entity or designee, or as may be required by law. The employing entity or designee shall complete promptly any of these revisions in the offering material so as not to delay or otherwise interfere with the group enrollment period.

(c) *Group enrollment period; prohibition of waiting periods, exclusions, and limitations.* An employing entity or designee including the option of membership in a qualified HMO under this subpart as part of the health benefits plan offered to its eligible employees shall provide for a group enrollment period, prior to the effective date of the HMO coverage established under paragraph (g) of this section, without application of waiting periods or exclusions or limitations based on health status as a condition of enrollment in the HMO or transfer to non-HMO coverage from an HMO. Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers which are included in the health benefits plan.

(d) *Continued availability of other health benefits.* (1) At the request of a qualified HMO, the employing entity or its designee shall provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and which are not included in the services provided by the HMO to its members as part of the HMO prepaid benefit package.

(2) For purposes of this paragraph, the term "free-standing" refers to a benefit which (i) is not integrated or incorporated into a basic health benefits package or major medical plan, and (ii) is either (A) offered by a carrier other than the one offering the basic health benefits package or major medical plan, or (B) subject to a separate premium from the premium for the basic health benefits package or major medical plan.

Illustrative Examples: Set forth below are examples of the employing entity's obligation with respect to the continued eligibility of employees selecting the HMO option for these free-standing health benefits:

1. The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide for the continued eligibility of those employees selecting the HMO option for dental coverage.

NOTE: If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.

2. If the non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eye glasses), and the HMO does not, the employing entity must provide for the continued eligibility for those employees selecting the HMO option for optical coverage.

3. The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its prepaid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide for the continued eligibility for dental coverage for those employees selecting the HMO option, although it is free to do so.

(e) *Affirmative written selections.* (1) During the group enrollment period in which the alternative of membership in any particular qualified HMO is offered to an eligible group of employees for the first time, the employing entity or designee shall present the health benefits plan alternatives to each eligible employee residing in the service area of the HMO with the requirement that an affirmative written selection be made among the different alternatives included in the health benefits plans. In subsequent group enrollment periods, it shall make available a selection among the alternatives; however, a written selection is required only when the eligible employee elects to change from one alternative to another.

(2) In addition to the group enrollment period, the employing entity or designee shall make available the opportunity to select among different existing alternatives within a health benefits plan to eligible employees who: (i) Are new employees, (ii) have been transferred or have changed their place of residence, resulting in eligibility for membership in a qualified HMO for which they were not previously eligible by place of residence, or resulting in residence outside the service area of a qualified HMO in which they were previously enrolled, or (iii) are covered by any alternative which ceases operation. At the time these employees are eligible to participate in the health benefits plan, the employing entity or designee shall make available, without waiting periods or exclusions or limitations based on health status as a condition, the opportunity to enroll in an alternative HMO or transfer to a non-HMO coverage from an HMO, and shall require these employees to make an affirmative written selection among the different alternatives included in the health benefits plan.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for is to be made as follows:

(1) For those employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For those employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services to be offered to eligible employees is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO alternatives in its health benefits plan.

(3) In all cases, the HMO has the right to include with its basic health services provided to its members for a basic health services payment, on a non-negotiable basis, those supplemental health services (i) that are required to be offered under State law, or (ii) that are included uniformly by the HMO in its prepaid benefit package, or (iii) coverage for which is available to employees selecting the non-HMO option but not available to employees selecting the HMO option.

(g) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, the effective date of coverage by the HMO for employees selecting the HMO option shall begin on the day the non-HMO coverage expires or is renewed without lapse.

§ 110.807 When the HMO is to be offered to employees.

The employing entity or designee shall offer eligible employees the option of membership in a qualified HMO at the earliest date permitted under the terms of existing collective bargaining agreements, employer-employee or public entity-employee contracts, or contracts for health benefits. Should the HMO's request for inclusion in a health benefits plan be received at a time when these existing contracts or agreements do not provide for including a qualified HMO in the health benefits plan, the inclusion of the HMO in the health benefits plan shall occur at the time that new agreements or contracts are offered or negotiated and shall be consistent with the following paragraphs:

(a) Unless mutually agreed otherwise, if a collective bargaining agreement is in force at the time the request for inclusion in the health benefits plan is made by the HMO to the employing entity or designee, the request shall be raised in the collective bargaining process (1) when a new agreement is negotiated, (2) if the agreement is for a fixed term in excess of one year and provides that its terms regarding health benefits may be renegotiated during the term of the agreement, at the times provided by the agreement for discussion of these changes, or (3) in accordance with a specific process to review HMO offers.

(b) Unless mutually agreed otherwise, for those employees not covered by a collective bargaining agreement, the employing entity or designee shall include the HMO option in any health benefits plan offered to eligible employees when the existing employer-employee contract or public entity-employee contract is renewed or when a new health benefits contract or other arrangement is negotiated. If an employer-employee or public entity-employee contract or a health benefits contract has no fixed term or has a term in exess of one year, the contract shall be treated as renewable on its earliest anniversary date. If the employing entity or designee is self-insured, the budget year shall be treated as the term of the existing contract.

(c) Unless mutually agreed otherwise, for employing entities with multiple contracts or other arrangements included as part of the health benefits plan which may have different expiration or renewal dates, the employing entity shall include the HMO option, in accordance with paragraphs (a) and (b) of this section, for each contract or arrangement at the time the contract or arrangement is renewed or reissued or the benefits provided under the contract or arrangement are offered to employees.

§ 110.808 Contributions for HMO option.

(a) *General principles.* (1) The employing entity or designee shall include the HMO option in the health benefits plan on terms no less favorable, with respect to the employing entity's monetary contribution or designee's cost for health benefits calculated in dollars and cents, than those on which the other alternatives in the health benefits plan are included. However, the employing entity or designee is not required to pay more for health benefits as a result of offering the option of membership in a qualified HMO than it would otherwise be required to pay for health benefits by a collective bargaining agreement or other employer-employee contract or public entity-employer contract in effect at the time the HMO is included in the health benefits plan.

(2) An employing entity or designee which calculates the health benefits contribution on a per employee earnings level basis must apply that same calculation to the HMO contribution. The amount of the employing entity's or designee's contribution per employee for the HMO option must be equal, in terms of dollars and cents, to the largest amount of the contribution that would be paid for that individual employee to any other alternative which is included in the health benefits plan, but shall not be required to exceed the amount of the HMO premium.

(3) The employing entity or designee shall increase the amount of its contribution for the HMO option at the time the contribution to other alternatives in the health benefits plan in-

creases (up to the amount of the HMO premium), unless (i) the employing entity's or designee's contribution is fixed by a contract or other arrangement between the employing entity or designee and the HMO, or (ii) otherwise agreed to by the employing entity or designee and the HMO.

(b) *Administrative expenses.* The employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan in determining the amount of its contribution to the HMO. However, if the employing entity or designee has special requirements for other than standard solicitation brochures and membership literature, it shall determine and distribute any administrative costs attributable to these requirements, in the case of the offering of the HMO option, in a manner consistent with its method of determining and distributing these costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or designee's cost for the HMO option, the employing entity or designee may exclude those portions of the contribution allocable to benefits (e.g., life insurance or insurance for supplemental health benefits) for which eligible employees or eligible employees and their eligible dependents will be covered notwithstanding selection of membership in an HMO, and which are not offered on a prepaid basis by the HMO to the employing entity's employees.

(d) *Contributions determined by collective bargaining agreements or by other contracts or by law.* Where the specific amount of the employing entity's contribution for health benefits is fixed by a collective bargaining agreement, by an employer-employee or public entity-employee contract, or by law, the amount so determined shall constitute the employing entity's obligation for contribution toward the HMO premiums on behalf of eligible employees or eligible employees and their eligible dependents.

(e) *Allocation of portion of a contribution determined by a collective bargaining agreement.* Where the employing entity's contribution for health benefits is determined by a collective bargaining agreement, but the amount so fixed includes contribution for benefits in addition to health benefits, the employing entity shall determine, or shall instruct its designee to determine, the portion of its contribution applicable to health benefits in accordance with paragraph (g) of this section.

(f) *Contributions not determined by collective bargaining agreements or by other contracts or by law.* For employees not covered by a collective bargaining agreement, employer-employee or public entity-employee contract, or by a law specifying the contribution for health benefits, the employing entity's contribution to the HMO on behalf of eligible employees or eligible employees and their eligible dependents shall be determined in accordance with paragraphs (a), (b), (c), and (g) of this section on the basis of the total cost of providing the health benefits offered to the employees for the most recent period for which experience is available.

(g) *Calculation of cost.* An employing entity's contribution or designee's cost for alternatives other than the qualified HMO, included in the health benefits plan shall be determined in the following manner, unless otherwise agreed to by the HMO and the employing public entity or designee:

(1) *Prospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined solely on the basis of a fixed prospective amount (not subject to retrospective adjustment) then the amount of the prospective payment made by or on behalf of the employing entity to the non-HMO alternative for the provision of health benefits to eligible employees or to eligible employees and their eligible dependents shall constitute the employing entity's contribution toward the HMO premium.

(2) *Retrospective calculation.* If the employing entity's contribution or designee's cost for non-HMO alternative health benefits is determined by a contract with a carrier on any form of retrospective experience rating basis, including any determination of current

premiums which reflects, takes into account, or is otherwise based on any form of supplementation or any rebate, refund or other redistribution of premiums collected in any previous year for which experience is available, any billing contract arrangement, any plan of self-insurance, any direct service plan provided by the employing entity or designee, or any other form of health benefits plan wherein the actual cost to the employing entity or designee is determined retrospectively, an estimated cost shall be used to determine the obligation for contribution toward the HMO premium. The employing entity or designee shall determine this estimated cost based on consideration of the following factors: (i) The employing entity's or designee's cost experience for the non-HMO alternatives with respect to the most recent benefit period for which the experience is available at the time when the employing entity's prospective contribution or designee's obligation to the HMO is to be determined; (ii) a reasonable allowance for inflation based on historical cost trends and the anticipated future costs increases; (iii) where applicable and consistently applied, cost differences experienced in the provision of health benefits for separate regional or local areas of employment; (iv) anticipated changes in the composition and experience of the covered population actually being served by the non-HMO alternatives attributable to the shift of enrollment to the HMO; (v) any changes in health benefits to be provided by the non-HMO alternatives during the period for which the estimated contribution is to be determined; (vi) any other anticipated material change in the experience rating basis under any health benefits contract for the benefits period.

(h) *Retention of data.* An employing entity or designee shall retain the data used to compute its level of contribution to the alternatives included in the health benefits plan for three years. The Secretary may review this data either on her own initiative or in response to a request to the Secretary from an HMO or an employee of the employing entity which sets forth reasonable grounds supporting the request to determine whether the level of contributions determined by the employing public entity or designee complies with this subpart.

§ 110.809 Payroll deductions.

Each employing entity which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required, and which is required by § 110.802(a) to offer its employees the option of membership in a qualified HMO, shall, with the consent of an employee who exercises this option, arrange for the employee's contribution, if any, for HMO membership to be paid through payroll deductions.

§ 110.810 Relationship of Section 1310 of the Public Health Service Act to the National Labor Relations Act, as amended, and the Railway Labor Act, as amended.

The obligation of an employing entity subject to this subpart to include the option of membership in a qualified HMO in any health benefits plan offered to its eligible employees shall be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

Subpart I—Continued Regulation of Health Maintenance Organizations and Other Entities

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1316, as amended, 90 Stat. 1945-1960 (42 U.S.C. 300e-300e-15).

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted.

§ 110.901 Purpose and applicability.

This subpart applies to any entity which was determined by the Secretary to be a qualified health maintenance organization (HMO) under Subpart F of this part, or which provided written assurances to the Secretary as a condition for receiving financial assistance under Subparts C, D, or E of this part, and sets forth procedures for enforcing the assurances given to the Secretary by these entities.

§ 110.902 Compliance with assurances.

Any entity subject to this subpart shall comply with the assurances which it provided to the Secretary, unless compliance is waived under § 110.907.

§ 110.903 Reporting requirements.

Entities subject to this subpart shall submit:

(a) The reports which may be required by the Secretary under § 110.108(j), and,

(b) Any additional reports the Secretary may reasonably require.

[43 FR 32255, July 25, 1978, as amended at 47 FR 19341, May 5, 1982]

§ 110.904 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file a written complaint with the Secretary with respect to the compliance of any entity with assurances it gave to the Secretary under this part. A complaint shall state the grounds and underlying facts of the complaint, the names of all persons involved, and that all appropriate grievance and appeals procedures established by the entity and available to the complainant have been exhausted.

(b) *Investigations.* The Secretary may initiate investigations when, based on a report, a complaint, or any other information, he has reason to believe that an entity subject to this subpart is not in compliance with any assurances it gave to the Secretary under this part. The Secretary will notify the entity in writing when an investigation has been initiated. He will include in this notice a full statement of the pertinent facts and of the matters being investigated, and a statement that the entity may submit to him within 30 days from the date of the notice a written report concerning these matters. The Secretary will obtain any information he considers necessary to determine the issues and may employ site visits, public hearings, or any other procedures he considers appropriate to obtain this information.

(c) *Determinations and notifications by the Secretary*—(1) *Determinations.* On the basis of his investigation, the Secretary will determine whether the entity has failed to comply with any assurances it gave to the Secretary under this part. The Secretary will publish in the FEDERAL REGISTER a notice regarding each determination of noncompliance. In the case of a qualified HMO, a determination of noncompliance shall not affect its status as a qualified HMO, unless the Secretary makes the further determination described in paragraph (d)(1) of this section.

(2) *Notification of determination; corrective action.* The Secretary will notify the entity in writing of his determination. This notice shall specify the manner in which the entity has not complied with its assurances and shall direct the entity to initiate corrective action which the Secretary deems necessary to bring the entity into compliance. The entity shall initiate this corrective action within 30 days of the date on which the notice is issued by the Secretary or within any longer period which the Secretary determines to be reasonable and specifies in the notice. The entity shall carry out the corrective action within the period specified for that purpose by the Secretary. In the notice, the Secretary may provide the entity an opportunity to submit for his approval proposed methods for achieving compliance.

(d) *Remedies*—(1) *Qualified HMO's:* If the Secretary determines that a qualified HMO (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, the Secretary will, for purposes of section 1310 of the act, revoke the HMO's qualification and will notify the HMO of this action. In this notification, the Secretary shall provide the HMO with an opportunity for reconsideration of the revocation, including at the HMO's election a fair hearing. The revocation of qualification shall be effective on the fifth working day after the HMO receives the notice unless the Secretary receives a request for reconsideration by that date. If, upon reconsideration, the Secretary again determines to revoke the HMO's qualification, this revocation shall be effective on the fifth working day after the HMO received notice of the reconsidered decision. The Secretary shall publish in the FEDERAL REGISTER each determination under this subparagraph. A revocation under this subparagraph shall have the effect described in § 110.905. Within 15 days after the date a notice of revocation is issued by the Secretary, the HMO shall, in a notice written in readily understandable language, describe the reasons for the determination that it is not a qualified HMO and shall send the notice to:

(i) The members of the HMO;

(ii) Each employer or public entity which has offered membership in the HMO in compliance with section 1310 of the act; and

(iii) Each lawfully recognized collective bargaining representative or other employee representative which represents the employees of the employer or public entity.

(2) *Other entities.* If, in the case of an entity which received a grant, loan, or loan guarantee under this part, the Secretary determines that it (A) has failed to initiate corrective action in accordance with paragraph (c)(2) of this section, or (B) has not carried out or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, he may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with any assurances it furnished the Secretary respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under title XIII for the grant, loan, or loan guarantee.

(3) *Reimbursement of members for services improperly denied or for charges improperly imposed.* If, in the case of an HMO with respect to which a determination of non-compliance has been made under paragraph (c)(1) of this section the Secretary also finds that the HMO has failed to provide or arrange for health services for its members in accordance with assurances given by the HMO to him under this part, or that the HMO has provided health services but has charged the member in a manner inconsistent with these assurances, he may, in addition to the remedies listed in paragraph (d) (1) and (2) of this section, require the HMO to reimburse its members for the expenses of securing basic or supplemental health services which because of this noncompliance the members obtained other than through the HMO or for which it charged the member. The provisions of this subparagraph shall apply without regard to when the HMO failed to comply with the appropriate assurances.

[43 FR 32255, July 25, 1978, as amended at 47 FR 19341, May 5, 1982]

§ 110.905 Effect of revocation of qualification for purposes of section 1310.

When an HMO's qualification is revoked under § 110.904(d)(1):

(a) The HMO may not seek inclusion in employees' health benefits plans under Subpart H of this part.

(b) With respect to employers including the HMO in the health benefits plan offered their employees, the HMO is not a qualified HMO for purposes of Subpart H of this part. Following the effective date of revocation, the inclusion of the health maintenance organization in an employees' health benefits plan will be disregarded for purposes of determining whether, and to what extent, the employer is subject to Subpart H of this part, and will not constitute compliance with the requirement of Subpart H of this part.

(c) The HMO is not a qualified HMO for purposes of the financial assistance programs under Subparts C, D, and E of this part until it is, in accordance with § 110.906, again qualified under subpart F of this part.

(d) The revocation of qualification shall be effective on the 5th working day after the HMO receives the notice.

§ 110.906 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by the Secretary for purposes of section 1310 of the act may, after completing the corrective action required under § 110.904(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart F of this part.

§ 110.907 Waiver of assurances.

The Secretary may release an entity from compliance with any assurances given under this part for good cause shown, consistant with the purpose of title XIII of the act, except that upon the waiver of any assurance regarding the HMO's compliance with section 1301 of the act, the Secretary will revoke the qualification of the HMO unless the waiver is based on paragraph (c) of this section. Grounds upon which the Secretary will find good cause include, but are not limited to, the following:

(a) The entity has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances;

(b) State laws governing the entity have been changed after it signed the assurances so as to prohibit the entity from being organized and operated in a manner consistent with the signed assurances, except to the extent that the changes would be superseded under the authority of section 1311 of the Act; or

(c) Qualification requirements have been changed by a law of the United States.

Subpart J—Loans and Loan Guaranteees for Acquisition and Construction of Ambulatory Health Care Facilities

AUTHORITY: Sec. 215 of the public Health Service Act, as amended, 58 Stat. 690 (42 U.S.C. 216); secs. 1301-1318 of the Public Health Service Act, as amended, 92 Stat. 2131-2141 (42 U.S.C. 300e-300e-17).

SOURCE: 45 FR 24353, Apr. 9, 1980, unless otherwise noted.

§ 110.1001 To what loans and loan guarantees do these regulations apply?

The regulations of this subpart, in addition to the regulations of Subpart B of this part, apply to loans and loan guarantees awarded to HMOs under section 1305A of the Public Health Service Act. These loans and loan guarantees are for projects for the acquisition of, the construction of, or the acquisition of equipment for, ambulatory health care facilities.

§ 110.1002 Definitions.

In addition to the terms defined in § 110.101 of this part:

"Ambulatory health care facility" or "facility" means a health care facility for the provision of diagnostic, treatment, and prevention services to ambulatory patients. If a facility occupies a portion of a building, the other parts of which are not owned by the HMO, the term does not include those other parts of the building. If an HMO is located in several buildings, each building in which the HMO provides diagnostic, treatment, and prevention services to ambulatory patients is a facility.

"Construction" means (a) the construction of new facilities; (b) the alteration, expansion, remodeling, replacement, and renovation of existing facilities; (c) off-site improvements in connection with an activity described in clause (a) or (b); and (d) the acquisition of land in connection with an activity described in clause (a), (b), or (c).

"Equipment" means those items which are necessary for the functioning of a facility acquired or constructed with a loan or loan guarantee awarded under this subpart, but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms and housekeeping supplies.

"Net assignable square footage" means the sum of all useable floor space measured on a floor plan to the inside faces of all enclosing walls or to lines denoting functional separations. Net assignable square footage includes all rooms to which a specific use can be assigned and excludes corridors, lobbies, toilets, mechanical shafts, ducts, electrical shafts or closets, elevators or elevators shafts, columns, exterior walls or partitions, service rooms, custodial supplies and general storage areas.

"Title" when used with reference to a facility which is proposed to be acquired or constructed with assistance under this subpart, means a fee simple or any other estate or interest (including a leasehold) which the Secretary finds sufficient to assure, for a period of not less than the repayment period of the loan to be made or guaranteed by the Secretary, undisturbed use and possession for the purposes of acquisition, or construction, and operation of the project.

§ 110.1003 What organizations are eligible for loans and loan guarantees?

(a) Any public health maintenance organization which is qualified under Subpart F of this part is eligible to apply for a loan under this subpart.

(b) Any private health maintenance organization which is qualified under Subpart F of this part is eligible to apply for a loan or a loan guarantee under this subpart.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19341, May 5, 1982]

§ 110.1004 What are the requirements for an application?

(a) An applicant shall submit an application for a loan or loan guarantee to the Secretary at the time and in the form and manner that the Secretary prescribes.

(b) An application must contain an appraisal of the property to be acquired with a loan made or guaranteed under this subpart. The appraisal must be prepared by an independent appraiser approved in advance by the Secretary.

(c) (1) An application must identify any party in interest (as defined in § 110.101 of this part) with whom a transaction is proposed and for which transaction assistance is being requested under this subpart. The application must also identify any individual who would become a party in interest as a consequence of a proposed transaction.

(2) Where a party in interest is so identified, the application must include:

(i) An explanation of the involvement of the party in interest;

(ii) A combined financial statement for the HMO and the party in interest. This statement must be prepared by an independent auditor in accordance with generally accepted accounting principles with appropriate opinions and notes, and in the form and manner prescribed by the Secretary;

(iii) A second appraisal of property to be acquired from the party in interest. This second appraisal is in addition to that required under paragraph (b) of this section and must be prepared by another independent appraiser approved in advance by the Secretary;

(iv) Evidence that the cost of each proposed transaction with a party in interest is consistent with prudent management and the fiscal soundness requirements in 42 CFR 110.108(a)(1); and

(v) Evidence that the transaction will not adversely affect the management decisions or the fiscal soundness of the HMO. For example, a description of procedures which will prevent the party in interest from controlling decisions by the HMO will respect to the facility to be constructed or acquired under this subpart would meet this requirement.

(3) The Secretary will disapprove an application where he or she determines that the participation of a party in interest is likely to affect adversely the administration and fiscal soundness of the HMO or its delivery of health services.

(d) An application must include an assurance satisfactory to the Secretary that the HMO will have title (as defined in § 110.1002) to the facility.

(e) An application must include an assurance satisfactory to the Secretary that the HMO will continue to comply with the restrictions on capacity set out in § 110.1007(b) for the five years following completion of acquisition or construction.

(f) An application must include line drawings of the proposed facility demonstrating that the allocation of square footage complies with the requirements of § 110.1007.

(g) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this part, and the terms of the loan documents and the loan guarantee, if any.

Editorial Note: Section 110.1004 set forth below was published at 47 FR 19342, May 5, 1982. The effectiveness of § 110.1004 is pending OMB review. A document will be published in the Federal Register announcing the results of OMB's review and the effective date of § 110.1004 if approved. Section 110.1004 set forth above remains in effect until further notice.

§ 110.1004 What requirements must an applicant meet?

(a) An applicant shall provide an appraisal of the property to be acquired with a loan made or guaranteed under this subpart. The appraisal must be prepared by an independent appraiser approved in advance by the Secretary.

(b)(1) An applicant shall identify any party in interest (as defined in § 110.101 of this part) with whom a transaction is proposed and for which transaction assistance is being requested under this subpart. The applicant must also identify any individual who would become a party in interest as a consequence of a proposed transaction.

(2) Where a party in interest is so identified, the applicant shall provide:

(i) An explanation of the involvement of the party in interest;

(ii) A combined financial statement for the HMO and the party in interest. This statement must be examined by an independent auditor in accordance with generally accepted accounting principles with appropriate opinions and notes;

(iii) Evidence that the proposed transaction with a party in interest will be consistent with the requirements of Subpart A of this part (for example, the fiscal soundness requirements in 42 CFR 110.108(a)(1)).

(c) The applicant shall provide an assurance satisfactory to the Secretary that the HMO will have title (as defined in § 110.1002) to the facility.

(d) The applicant shall include line drawings of the proposed facility demonstrating that the allocation of square footage complies with the requirements of § 110.1007.

(e) The applicant shall provide assurances satisfactory to the Secretary that:

(1) At the time the application is made the HMO is fiscally sound;

(2) If the application is for a loan, the HMO is unable to secure a loan, at the rate of interest prevailing in the area in which the organization is located, from non-Federal lenders for the project with respect to which the application is submitted, or, if the application is for a loan guarantee, the HMO would be unable to secure a loan from such lenders for the project without the loan guarantee; and

(3) During the period of the loan or loan guarantee, the HMO will remain fiscally sound.

[47 FR 19342, May 5, 1982]

§ 110.1005 What information must be submitted by an applicant which has received a commitment for a loan to be made or guaranteed under this subpart before the closing of the loan?

(a) Design, bid, and contract documents for each project must be prepared in accordance with all of Part 2.1 (except sections 5.4, 8.8, 11.2, 11.3, 11.4, Chapter 12, sections 13.2, 13.3 and Exhibits 9 and 10) of DHHS *Technical Handbook for Facilities Engineering and Construction Manual, Federally Assisted Construction,* entitled "2.1 Information for Project Applicants and State Agencies on Design and Construction Related Activities." With these exceptions, Part 2.1 is incorporated into this subpart by reference. This part of the Handbook will be provided to all applicants and is available at cost to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This part of the Handbook is also available for inspection without charge at these offices. If this handbook is amended, a notice of the amendments will be published in the Federal Register and a copy of the amendments will be on file at the Office of the Federal Register. The design, bid, and contract documents must be submitted to the Secretary for approval before the closing of a loan to be made or guaranteed under this subpart.

(b) The plans and specifications for the design and construction of, and equipment for, a facility submitted to the Secretary must conform with:

(1) State and local codes, laws, and ordinances, and

(2) Chapter 14 of DHHS Publication No. (HRA) 79-14500, *Minimum Requirements of Construction and Equipment for Hospitals and Medical Facilities*, "Small Primary Health Care Centers," except for the last sentence of paragraph 14.1A, the parenthetical phrase "(usually 4)" in paragraph 14.1B(1) and paragraph 14.1B(3) in its entirety. With these three exceptions, Chapter 14 of this document is incorporated into this subpart by reference. This publication will be provided to all applicants and is available for the cost of reproduction to any interested person upon request to the Office of Health Maintenance Organizations in any of the Department's Regional Offices. The addresses of Regional Offices are listed in 45 CFR 5.31(b). This publication is also available for inspection without charge at these offices. If this publication is amended, a notice of the amendments will be published in the FEDERAL REGISTER and a copy of the amendments will be on file at the Office of the Federal Register.

Incorporation by reference provisions approved by the Acting Director of the Federal Register on October 22, 1979.

§ 110.1006 What are the limitations on loans and guaranteed loans?

(a) The aggregate amount of principal of loans made or guaranteed, or both, for an ambulatory health care facility under this subpart may not exceed the amount specified by section 1305A(c)(1) of the Act.

(b) The aggregate amount of loans made or guaranteed under this subpart for a project may not exceed 90 percent of the eligible costs of the project unless the Secretary, for good cause, approves a greater percentage.

(1) In determining whether there is good cause for approving a greater percentage, the Secretary will consider:

(i) The availability of other sources of funds to the applicant;

(ii) The effect on the security for the loan of other borrowing by the applicant to pay for the remainder of the project costs; and

(iii) Any other factors the Secretary determines are consistent with the purposes of the Act.

(2) The applicant may not use any funds provided under other subparts of this part to pay for the applicant's portion of eligible costs for a project assisted under this subpart.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19342, May 5, 1982]

§ 110.1007 What requirements apply to projects assisted under this subpart?

Projects assisted or to be assisted under this subpart must comply with the following requirements, unless a requirement is waived or modified by the Secretary for good cause.

(a) *Net assignable square footage limitations applicable to a facility.* The following limitations apply to an assisted facility, including any portion of the facility acquired or constructed (or to be acquired or constructed prior to the termination of the 5-year period following acquisition or construction) without Federal assistance under this subpart:

(1) Not more than 25 percent of the net assignable square footage (as defined in 110.1002) may be devoted to administrative functions of the HMO. The remainder must be devoted to clinical use. For the purpose of this paragraph, (i) administrative functions include general administration, marketing, enrollment and claims processing, and (ii) clinical uses of space include medical records storage, clinical administration, and space for the provision of basic health services, health education, and pharmacy, optical, dental, laboratory, X-ray, and other health services.

(2) At least 50 percent of the net assignable square footage must be for the provision of basic health services (as defined in Subpart A of this part).

(b) *Net assignable square footage limitations applicable to an HMO.* The following limitations apply to the net assignable square footage of all the facilities to be available to the HMO during the five year period following the completion of the acquisition or construction to be assisted under this subpart. This includes any net assignable square footage available or to be available to the HMO for the purposes specified below, whether or not acquired or constructed with assistance under this subpart:

(1) The net assignable square footage available to the HMO may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

(2) Where assistance under this subpart is used to acquire or construct facilities for the provision of optical, pharmacy or dental services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the five year period after the acquisition or construction is to be completed. Only the HMO members projected to be enrolled to receive these services on a prepaid basis may be counted for purposes of this limitation. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

(3) Where assistance under this subpart is used to acquire or construct facilities for the provision of laboratory or X-ray services, the total net assignable square footage available to the HMO for the provision of each of these assisted services may not exceed that needed to serve 110 percent of the projected number of HMO members at the end of the 5 year period after the acquisition or construction is to be completed. The applicant shall calculate the amount of net assignable square footage which is needed in accordance with instructions provided by the Secretary.

[45 FR 24353, Apr. 9, 1980, as amended at 47 FR 19342, May 5, 1982]

§ 110.1008 What is an eligible cost?

(a) The Secretary will consider only eligible costs in determining the amount of a loan to be made or guaranteed under this subpart. Eligible costs are those which are reasonable and necessary for the acquisition or construction of, or the purchase of equipment for, a facility or portion of a facility. Costs which the Secretary determines to be inappropriate to the needs of a particular HMO and other costs which the Secretary specifies in materials to be provided to each applicant are not eligible costs.

(b) The cost of acquisition of equipment is an eligible cost only if the equipment is for a facility acquired or constructed, or to be acquired or constructed, with a loan made or guaranteed under this subpart.

(c) Acquisition of land for a facility is an eligible cost only if it is in connection with the acquisition or construction of a facility on that land.

(d) The costs of leasing land, a facility, or equipment for a facility are not eligible costs. The costs of construction on leased land, including renovation of a leased facility, may be eligible costs if adequate security is available to protect the financial interests of the United States.

(e) The cost of repaying an interim construction loan for a facility is an eligible cost.

§ 110.1009 What security is required?

(a) Each loan made by the Secretary shall bear interest at a rate comparable to the current rate prevailing, with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges. The Secretary may set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date the disbursement is made for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(b) Each loan guaranteed by the Secretary shall bear interest at a rate the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States.

[47 FR 19342, May 5, 1982]

§ 110.1010 How and over what period are loans and guaranteed loans to be repaid?

(a) The principal amount of each loan or guaranteed loan, together with interest thereon, must be repayable in accordance with a repayment schedule which is to be agreed upon by the parties to the loan, or by the parties to the guaranteed loan and the Secretary, prior to or at the time of the closing of the loan. Unless otherwise authorized by the Secretary, each loan made or guaranteed by the Secretary must be repayable in substantially level installments of interest and principal (except as provided in paragraph (b) of this section) sufficient to amortize the loan through the final year of the life of the loan.

(b) Interest on the unpaid principal amount of the loan shall be due and payable not less frequently than semiannually from the date of the initial disbursement of funds under the loan. Principal repayments shall be paid not less frequently than semi-annually but may be deferred until completion of the project.

(c) Each loan or guaranteed loan shall be repayable over a period approved by the Secretary, not to exceed 25 years beginning on the date of closing of the loan.

(1) The Secretary may approve a repayment period of less than 25 years in particular cases if he or she determines that a shorter repayment period is more appropriate to an applicant's total financial plan and not inconsistent with the financial interests of the United States.

(2) A loan repayment period may not exceed the estimated useful life of the facility to be acquired or constructed with the assistance of the loan. In the case of a loan solely for acquisition of equipment for a facility previously assisted under this subpart, the loan repayment period may not exceed the estimated useful life of the most expensive items of equipment.

(3) Where a leased facility is being constructed (i.e., renovated) with assistance under this subpart, or a facility is being acquired or constructed on leased land with assistance under this part, the loan repayment period may not be longer than the period of the lease.

[45 FR 24353, Apr. 9, 1980. Redesignated at 47 FR 19342, May 5, 1982]

§ 110.1011 On what basis may the Secretary waive rights of recovery?

In determining whether there is good cause for waiver of any right of recovery which the Secretary may have against an HMO, either because of a loan made under this subpart or because of a payment made under a loan guarantee under this subpart, he or she will take into consideration the extent to which:

(a) The recipient of the loan or guaranteed loan or other owner of the facility with respect to which the loan or loan guarantee was made will continue to use it for (1) the purpose for which it was constructed or (2) another public or nonprofit purpose which will promote the purposes of the Act;

(b) There are reasonable assurances that for the remainder of the repayment period of the loan, other public or nonprofit facilities not previously used for the purpose for which the facility was constructed will be so used and are substantially equivalent in nature and extent for that purpose;

(c) The recovery would seriously curtail the provision of medical services to persons in need of these services in the area; and

(d) It is likely that payment can be obtained which would be greater than the costs the government would incur as a result of continuing to pursue collection.

[45 FR 24353, Apr. 9, 1980. Redesignated at 47 FR 19342, May 5, 1982]

SUBCHAPTER K—HEALTH PLANNING AND RESOURCES DEVELOPMENT

PART 121—NATIONAL GUIDELINES FOR HEALTH PLANNING

Subpart A—General Provisions

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AUTHORITY: Sec. 1501 of the Public Health Service Act, 88 Stat. 2227 (41 U.S.C. 300k-1).

SOURCE: 43 FR 13044, Mar. 28, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 121.1 Definitions.

Terms used herein shall have the meanings given them in 42 CFR 122.1.

§ 121.2 Purpose and scope.

Section 1501 of the Public Health Service Act requires the Secretary to issue, by regulation, national guidelines for health planning. The guidelines are to include national health planning goals (section 1501(b)(2)) and standards respecting the supply, distribution, and organization of health resources (section 1501(b)(1)). This subpart includes general provisions applicable to such goals and standards; Subpart B of this part sets forth specific national health planning goals; and Subpart C sets forth specific standards respecting the supply, distribution, and organization of health resources.

§ 121.3 Applicability of national guidelines to Health Systems Plans.

Section 1513(b)(2) of the Act requires health systems agencies, in the development of their Health Systems Plans, to give "appropriate consideration" to the national guidelines for health planning. Health Systems Plans must also "take into account" and be "consistent with" the standards respecting the supply, distribution, and organization of health resources set forth in Subpart C.

(a) *Meaning of "consistent with."* A Health Systems Plan will be considered "consistent with" a standard set forth in Subpart C where it (1) establishes a target level which is not in excess of the level set forth in the standard where that level is stated as a maximum, or not less than the level set forth in the standard where that level is stated as a minimum, except where a specific adjustment is justified in accordance with Subpart C or § 121.6 of this subpart, and (2) includes plans which, if implemented, are reasonably calculated to achieve that target level within five years.

(b) *Effective date.* Health Systems Plans established after December 31, 1978, must be "consistent with" each standard set forth in Subpart C.

§ 121.4 Applicability of national guidelines to State health plans.

Each State's State health plan developed under Title XV of the act must be "made up of" the Health Systems Plans of the health systems agencies within the State, revised as found necessary by the Statewide Health Coordinating Council to achieve their appropriate coordination with each other or to deal more effectively with Statewide health needs. (Section 1524(c)(2)(A) of the Act.) Since Health Systems Plans must individually give appropriate consideration to the national guidelines for health planning and take into account and be consistent with the standards respecting the supply, distribution, and organization of health resources, the State health plan will accordingly reflect the guidelines.

§ 121.5 Responsibility of health systems agencies.

Subject to the authority of the Statewide Health Coordinating Council to require the revision of Health Systems Plans under section 1524(c)(2)(A) of the Act, each health systems agency is responsible for analyzing the needs and conditions in its health service area and applying the national guidelines for health planning in the development of its Health Systems Plan, including the need for adjustments.

§ 121.6 Adjustments of standards for particular Health Systems Plans.

Subpart C of this part includes provisions for adjustment of individual standards. In addition:

(a) Health systems agencies must make such adjustments as may be necessary:

(1) To take into account special needs and circumstances of Health Maintenance Organizations;

(2) To take into account services available to local residents from Federal health care facilities; and

(3) To take into account higher minimum target levels and lower maximum levels that are established for State Certificate-of-Need and related programs.

(b) Whenever a health systems agency concludes, on the basis of a detailed analysis, that development of a Health Systems Plan consistent with one or more of the standards set forth in Subpart C would result in:

(1) Residents of the health service area not having access to necessary health services;

(2) Significantly increased costs of care for a substantial number of patients in the area; or

(3) The denial of care to persons with special needs resulting from moral and ethical values; and that result cannot be avoided through use of the adjustments specifically provided for in the standard or in paragraph (a) of this section, the agency may include in the Health Systems Plan a special adjustment of the standard or standards which will avoid this result. Whenever a special adjustment is so included, the plan must also contain a detailed justification for the adjustment and documentation of the circumstances that are the basis of the justification. In the case of an adjustment included on the basis of (1) or (2) above, the plan must further include an analysis indicating whether the need for such an adjustment is permanent. If it is, the supporting rationale must be documented and it it is not, an estimate must be included of how long inclusion of the adjustment will be required along with a detailed justification for that length of time.

(c) Any proposed adjustment under this section and the analyses supporting it must be reviewed by the State health planning and development agency in its preparation or review of the preliminary State health plan under section 1523(a)(2) of the Act and by the Statewide Health Coordinating Council in its preparation or review of the State health plan under section 1524(c)(2) of the Act. On the basis of that review, and consistent with Statewide health needs and the need to coordinate Health Systems Plans as determined by the Statewide Health Coordinating Council, the adjustment may be made part of the State health plan. The Statewide Health Coordinating Council shall report its comments on and disposition of the proposed adjustments to the Secretary under section 1524(c)(1) of the Act.

Supbart B—National Health Planning Goals—[Reserved]

Subpart C—Standards Respecting the Appropriate Supply, Distribution, and Organization of Health Resources

§ 121.201 General hospitals—Bed supply.

(a) *Standard.* There should be less than four non-Federal, short-stay hospital beds for each 1,000 persons in a health service area except under extraordinary circumstances. For purposes of this section, short-stay hospital beds include all non-federal short-stay hospital beds (including general medical/surgical, children's, obstetric, psychiatric, and other short-stay specialized beds). Conditions which may justify adjustments to this ratio for a health service area include:

(1) *Age.* Individuals 65 years of age and older have a higher hospital utilization rate—up to four times that of the general population—than any other age group. Bed-population ratios for health service areas in which the percentage of elderly people is significantly higher (more than 12 percent of the population) than the national average may be planned at a higher ratio, based on analyses by the HSA.

(2) *Seasonal population fluctuations.* Large seasonal variations in hospital utilization may justify higher ratios. Plans should reflect vacation and recreation patterns as well as the needs of migrant workers and other factors causing usual seasonal variations.

(3) *Rural areas.* Hospital care should be accessible within a reasonable period of time. For example, in rural areas in which a majority of the residents would otherwise be more than 30 minutes travel time from a hospital, the HSA may determine, based on analyses, that a bed-population ratio of greater than 4 per 1,000 persons may be justified.

(4) *Urban areas.* Large numbers of beds in one part of a Standard Metropolitan Statistical Area (SMSA) may be compensated for by fewer beds in other parts of the SMSA. Health service areas which include a part of an SMSA may plan for bed-population ratios higher than 4 per 1,000 persons reflecting existing patterns if there is a joint plan among all HSAs serving the SMSA which provides for less than 4 beds per 1,000 persons in the SMSA as a whole.

(5) *Areas with referral hospitals.* In the case of referral institutions which provide a substantial portion of specialty services to individuals not residing in the area, the HSA may exclude from its computation of bed-population ratio the beds utilized by referred patients who reside outside both the SMSA and the HSA in which the facility is located.

(b) *Discussion.* There is general agreement that the number of general hospital beds in the United States is significantly in excess of what is needed and that utilization of acute in-patient care resources is often higher than necessary. Excess bed capacity and use contribute to the high cost of hospital care with little or no health benefits. Empty beds are often filled by patients who could be cared for as well or better in less expensive ways, such as ambulatory care or home care.

The Institute of Medicine's Report on "Controlling the Supply of Hospital Beds" in 1976 recommended that the nation should achieve at least a 10 percent reduction in the bed population ratio in the next five years and further significant reductions thereafter. The Institute statement noted: "This would mean a reduction from the current national average of approximately 4.4 non-Federal short-term general hospitals beds per 1,000 population to a national average of approximately 4 in five years and well below that in the years to follow." Similarly a study reported by InterStudy of Minneapolis, Minn., the same year concluded that a 10 percent reduction in hospital bed supply would be a desirable and reasonable first step toward reducing excess hospital capacity. As part of the process for determining this standard, the Department reviewed projections in State health facilities planning plans. Such plans have set targets for future hospital bed supply that, on an aggregate nationwide basis, project just under 4 beds per thousand. Many

States set lower targets. Health Maintenance Organizations and similar groups have shown that high quality care can be provided with less than 3 beds per 1,000 population. Thus, 4 beds per 1,000 population is a ceiling, not an ideal situation. HSAs are expected to identify the desirable local ratio, working closely with the State Health Planning and development Agency and the Statewide Health Coordinating Council. It is anticipated that in subsequent plans HSAs will be required to indicate how they will reach a bed-population ratio of less than 3.7 per 1,000 population except under extraordinary circumstances. HSAs whose areas are now below the 4 per 1,000 level are urged to attempt to decrease bed-population ratios below 3.7 per 1,000 population. In areas where Federal medical facilities and Health Maintenance Organizations provide substantial services to local residents, lower ratios should be readily achieveable. Population growth must be carefully analyzed; in many cases, this factor alone will bring the area below the target level if no unnecessary additional beds are built. Under some conditions, a higher target ceiling may be justified by the HSA. Travel distance to the nearest hospital is one of the most important factors to be analyzed, especially in rural areas. A planning criteria of 30 minutes has been set, in line with the policies of many local and State health planning agencies around the country. In analyzing ways of reducing bed supply, it should be recognized that greater savings will be achieved when entire facilities are considered. In developing such plans, priority consideration should be given to maintaining and strengthening resources that are emphasizing activities identified as national health priorities in section 1502 of the Act.

§ 121.202 General hospitals—Occupancy rate.

(a) *Standard.* There should be an average annual occupancy rate for medically necessary hospital care of at least 80 percent for all non-Federal, short-stay hospital beds considered together in a health service area, except under extraordinary circumstances. Conditions which may justify an adjustment to this standard for a health service area include:

(1) *Seasonal population fluctuations.* In some areas, the influx of people for vacation or other purposes may require a greater supply of hospital beds than would otherwise be needed. Large seasonal variations in hospital utilization which can be predicted through hospital and health insurance records may justify an average annual occupancy rate lower than 80 percent based on analyses by the HSA.

(2) *Rural areas.* Lower average annual occupancy rates are usually required by small hospitals to maintain empty beds to accommodate normal fluctuations of admissions. In rural areas with significant numbers of small (fewer than 4,000 admissions per year) hospitals, an average occupancy rate of less than 80 percent may be justified, based on analyses by the HSA.

(b) *Discussion.* There is substantial evidence that excess capacity and use contribute significantly to high hospital costs. The 1976 report by the Institute of Medicine, for example, found that "there is a growing concern that the surpluses of hospital beds are contributing significantly to the recent rise of health care costs at a rate well beyond that of general inflation. This concern has not only to do with the cost of maintaining unused hospital bed capacity, but also with the unnecessary and inappropriate uses of hospital beds, especially those in the short-term care category." Occupancy rates currently average about 75 percent nationwide. Many hospital capacity studies, including those by InterStudy and the Bureau of Hospital Administration of the University of Michigan, indicate that an average hospital occupancy rate exceeding 80 percent is a reasonable target. In addition, many State and local health planning agencies have established higher occupancy targets. For example, health planning agencies in Illinois, New Jersey, New York, Massachusetts, Michigan, and Wisconsin have recommended occupancy rates higher than 80 percent for larger hospitals. Higher averages have been advocated, especially for medical-surgical units. While past studies typically apply these rates to individual institutions, the Department, in line with the objectives of community-wide planning, has extended this concept to apply on an area-wide basis. Within local health service areas, hospitals of varying size and circumstances will have varying occupancy rates; a collective rate exceeding 80 percent on an area-wide basis is a reasonable, achievable goal except in rural areas and when situations present extraordinary circumstances. Increases are to be attained through constrained capacity growth and improved planning and management. It is not, of course, intended that increased rates be achieved through unnecessary hospital admissions or stays.

§ 121.203 Obstetrical services.

(a) *Standard.* (1) Obstetrical services should be planned on a regional basis with linkages among all obstetrical services and with neonatal services.

(2) Hospitals providing care for complicated obstetrical problems (Levels II and III) should have at least 1,500 births annually.

(3) There should be an average annual occupancy rate of at least 75 percent in each unit with more than 1,500 births per year.

(b) *Discussion.* The importance of developing regional systems of care for maternal and perinatal health services has been broadly recognized. The Committee on Perinatal Health, representing the American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the American Medical Association issued a report in 1976, "Toward Improving the Outcome of Pregnancy." The report identified opportunities to reduce rates of maternal, fetal and neonatal mortality as well as to improve deployment of scarce resources, especially those needed to provide comprehensive services for high-risk patients. The impact on quality of care of both under-utilization and over-utilization was emphasized.

The report states: "A systematized, cohesive regional network including a number of differentiated resources is the approach most likely to achieve the objective. Each component of the regional system must provide the highest quality care, but the degree of complexity of patient needs determines where, and by whom, the care should be provided." Level I hospitals provide services primarily for uncomplicated maternity and newborn cases. Level II hospitals provide services for uncomplicated cases and for the majority of complicated problems, and certain specialized neonatal services. Level III hospitals are able also to handle all the serious types of illness and abnormalities. Established arrangements should provide for early access of high-risk pregnant women and prompt referrals among levels of care as appropriate. Regional planning should include a cooperative, coordinated network of hospitals, physicians and other health care professionals, providing: (1) Expert consultation and referral (2) basic and continuing education for health professionals and consumers, (3) transport of selected patients to facilities possessing more specialized maternal and neonatal services, (4) a continuing evaluation of the effectiveness and costs of regionalized programs. In 1972 the American College of Obstetrics and Gynecology identified a minimal target of 1,500 births per year for facilities in communities of 100,000 population or more to provide a full range of obstetrical services in an efficient manner. In 1974, this figure was revised: "The experience of many obstetric departments indicate that the size, equipment, services and personnel adequate to maintain a consistently high standard of ordinary obstetrical care and a reasonably economic operation generally require more than 2,000 deliveries." (Standards for Obstetical and Gynecological Services, Committee on Professional Standards of the American College of Obstetricians and Gynecologists, 1974.) The Committee on Perinatal Health also identified the 2,000 minimum figure for facilities identified as Level II facilities. In detemining the 1,500 target, the Department took into consideration these reports as well as the comments received from the public and from members of the expert advisory panel, particularly the criticism that a 2,000 target was too high. The 1,500 level is in line with the policies of many local and State health planning agencies and can help assure more economic use of specialized resources while avoiding inappropriate utilization of such facilities. The Department also recognizes that there are substantial differences among facilities which provide different ranges of services, and there are circumstances, such as those involving special moral and ethical preferences, which may necessitate the HSA providing an adjustment to this standard. In addition, in order to promote more economical use of resources the Department has established the 75 percent minimum occupancy rate in Level II and III facilities. The 75 percent figure was derived from an analysis of various occupancy rate figures in a number of source documents, whose recommendations range from 50 percent to over 80 percent. The Hill-Burton program recommended an occupancy level for obstetrical units of at least 75 percent. The Department anticipates that institutions operating at Levels II and III will usually be able to exceed this level.

In keeping with the national priority set forth in Section 1502 of the Act for the consolidation and coordination of institutional health services, the consolidation of multiple, small obstetrical units with low occupancy rates should be undertaken unless such action is undesirable because of needs to assure ready access and sensitive care.

§ 121.204 Neonatal special care units.

(a) *Standard.* (1) Neonatal services should be planned on a regional basis with linkages with obstetrical services.

(2) The total number of neonatal intensive and intermediate care beds should not exceed 4 per 1,000 live births per year in a defined neonatal service area. An adjustment upward may be justified when the rate of high-risk pregnancies is unusually high, based on analyses by the HSA.

(3) A single neonatal special care unit (Level II or III) should contain a minimum of 15 beds. An adjustment downward may be justified for a Level II unit when travel time to an alternate unit is a serious hardship due to geographic remoteness, based on analyses by the HSA.

(b) *Discussion.* For this standard, the Department has adopted the widely endorsed concept of regionalization, involving various levels of care. Under this concept, Level III units are staffed and equipped for the intensive care of new-borns as well as intermediate and recovery care. Level II units provide intermediate and recovery care as well as some specialized services. Level I units provide recovery care. Neonatal special care is a highly specialized service required by only a very small percentage of infants. The Department believes that four neonatal special care beds for intensive and intermediate care per 1,000 live births will usually be adequate to meet the needs, taking into account the incidence of high risk pregnancies, the percentage of live births requiring intensive care, and the average length of stay. ("Bed" includes incubators or other heated units for specialized care and bassinettes.) In addition, the Department has established a minimum of 15 beds per unit for Levels II and III as the minimum number necessary to support economical operation for these services. Both standards are supported and recommended by the American Academy of Pediatrics. The American Academy of Pediatrics has noted that "the best care will be given to high risk and seriously ill neonates if intensive care units are developed in a few adequately qualified institutions within a community rather than within many hospitals. Properly conducted, early transfer of these infants to a qualified unit provides better care than do attempts to maintain them in inadequate units." This regionalized approach is reflected in the minimum size standard which is designed to foster the location of specialized units in medical centers which have available special staff, equipment, and consultative services and facilities. Since perinatal centers, which include neonatal units will serve the patient load resulting from a representative population of more than one million, a defined neonatal service area should be identified by the relevant HSAs in conjunction with the State Agency. Special attention should also be given to ensure adequate communication and transportation systems, including joint transfers of mother and child and maintenance of family contact. Hospitals with such units should have agreements with other facilities to serve referred patients. The regional plan should include a structured ongoing system of review, including assessment of changes in health status indicators.

§ 121.205 Pediatric inpatient services—Number of beds.

(a) *Standard.* There should be a minimum of 20 beds in a pediatric unit in urbanized areas. An adjustment downward may be justified when travel time to an alternate unit exceeds 30 minutes for 10 percent or more of the population, based on analyses by the HSA.

(b) *Discussion.* Pediatric services should be planned on a regionalized basis with linkages among hospitals and other health agencies to provide comprehensive care. The 1977 report of the Committee on Implications of Declining Pediatric Hospitalization Rates for the National Research Council states that "for a policy of housing children separately to be effective, certain minimum services and facilities are needed, thus requiring bed capacity utilization to make provision for these services and facilities economically feasible." This standard was developed by the Department in this context.

A number of sources support a minimum unit size of 20 pediatric beds, including planning agencies in California, Massachusetts, Ohio, Pennsylvania, and Wisconsin. Consolidation of pediatric care in units of at least 20 beds in urbanized areas will promote the concentration of nursing and support staff with special pediatric knowledge and skills, the increased training of staff, and the provision of special treatment and other ancillary facilities which meet the special needs of children. (A pediatric inpatient unit is a specific section, ward, wing, hospital or unit devoted primarily to the care of medical and surgical patients usually less than 18 years old, not including special care for infants.)

The criteria of 30 minutes travel time reflects interest in ensuring that children remain close to their homes, family and friends. Frequent visits to hospitalized children are highly desirable and can be an aid to improvement and recovery. The American Academy of Pediatrics has recommended to its State Chapters that child health plans should provide that primary care for children should be available within 30 minutes. This access standard is consistent with those of many local and State planning agencies such as those in Massachusetts, New York, Pennsylvania, and Wisconsin.

§ 121.206 Pediatric inpatient services—Occupancy rates.

(a) *Standard.* Pediatric units should maintain average annual occupancy rates related to the number of pediatric beds (exclusive of neonatal special care units) in the facility. For a facility with 20-39 pediatric beds, the average annual occupancy rate should be at least 65 percent; for a facility with 40-79 pediatric beds, the rate should be at least 70 percent; for facilities with 80 or more pediatric beds, the rate should be at least 75 percent.

(b) *Discussion.* Variable occupancy rates are designed to reflect the need for smaller units to maintain the capacity to accommodate normal day-to-day fluctuations in admissions and to set aside pediatric beds for particular ages and types of cases. Such scheduling problems are less severe in pediatric units of a greater capacity. Moreover, large units are able to sustain higher occupancy rates because they are frequently associated with regional centers which serve patients needing types of care that can be scheduled on a more flexible basis. It is not intended, of course, to encourage unnecessary admissions or stays to achieve these levels. This standard is identical to that recommended by the American Academy of Pediatrics.

§ 121.207 Open heart surgery.

(a) *Standard.* (1) There should be a minimum of 200 open heart procedures performed annually, within three years after initiation, in any institution in which open heart surgery is performed for adults.

(2) There should be a minimum of 100 pediatric heart operations annually, within three years after initiation, in any institution in which pediatric open heart surgery is performed, of which at least 75 should be open heart surgery.

(3) There should be no additional open heart units initiated unless each existing unit in the health service area(s) is operating and is expected to continue to operate at a minimum of 350 open heart surgery cases per year in adult services or 130 pediatric open heart cased in pediatric services.

(b) *Discussion.* Open heart surgery for congenital and acquired heart and coronary artery disease represents a marked advance in patient care. Highly specialized open heart procedures require very costly, highly specialized manpower and facility resources. Thus, every effort should be made to limit duplication and unnecessary resources related to the performance of open heart procedures, while maintaining high quality care. Minimum case loads are essential to maintain and strengthen skills. (Open heart surgery procedures are defined as procedures which use a heart-lung by-pass machine to perform the functions of circulation during surgery.) A minimum of 200 adult open heart surgery procedures should be performed annually within an institution to maintain quality of patient care and make most efficient use of resources. This standard is based on recommendations of the Inter-Society Commission on Heart Disease Resources. In order to prevent duplication of costly resources which are not fully utilized, the opening of new units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 procedures per year. The 350 level assumes an average of 7 operations a week, a schedule that in the Department's judgement is feasible in most institutions providing these services. In units that provide services to children, lower targets are indicated because of the special needs involved. The established level for pediatric units is consistent with the recommendation of the Pediatric Cardiology Section of the American Academy of Pediatrics. In determining the utilization target of 130 pediatric open heart cases, the Department used the same ratio as for adult units. In the case of units that provide services to both adults and children, at least 200 open heart procedures should be performed, including 75 for children. In some areas, open heart surgical teams, including surgeons and specialized technologists, are utilizing more than one institution. For these institutions, the guidelines may be applied to the combined number of open heart procedures performed by the surgical team where and adjustment is justifiable in line with §121.6(B) and promotes more cost effective use of available facilities and support personnel. In such cases, in order to maintain quality care a minimum of 75 open heart procedures in any institution is advisable, which is consistent with recommendations of the American College of Surgeons. Data collection and quality assessment and control activities should be part of all open heart surgery programs.

§ 121.208 Cardiac catheterization.

(a) *Standard.* (1) There should be a minimum of 300 cardiac catheterizations, of which at least 200 should be intracardiac or coronary artery catheterizations, performed annually in any adult cardiac catheterization unit within three years after initiation.

(2) There should be a minimum of 150 pediatric cardiac catheterizations performed annually in any unit performing pediatric cardiac catheterizations within three years after initiation.

(3) There should be no new cardiac catheterization unit opened in any facility not performing open heart surgery.

(4) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit in the health service area(s) is greater than 500 and no additional pediatric unit opened unless the number of studies per year in each existing unit is greater than 250.

(b) *Discussion.* The modern cardiac catheterization unit requires a highly skilled staff and expensive equipment. Safety and efficacy of laboratory performance requires a case load of adequate size to maintain the skill and efficiency of the staff. In addition, the underutilized unit represents a less efficient use of an expensive resource and frequently reflects unnecessary duplication. Based on recommendations from the Inter-Society Commission on Heart Disease Resources, the Department believes that a minimum level of 300 catheterizations per year is indicated to achieve economic use of resources. Several State health planning agencies, such as New Jersey, suggested a higher minimum level and the Department will be considering whether a higher level should be established in the future. The Department has also determined the existing units should be performing more than 500 cardiac catheterizations or 250 pediatric cardiac catheterizations before a new unit is opened. The 500 level is based on an average of two catheterizations a day, a rate that is in the Department's judgement readily achievable in most institutions providing these services and that will foster more effective use of current resources prior to the development of additional resources. More than 600 procedures are performed annually in some institutions. Pediatric cardiac catheterizations require special facilities and support services. Lower target numbers are presented in these cases because of the special conditions and needs of children. The established levels are consistent with the recommendations of the Section on Cardiology of the American Academy of Pediatrics and the Inter-Society Commission on Heart Disease Resources. The patient studied in the cardiac catheterization unit is frequently recommended for open heart surgery. While acceptable inter-institutional referral patterns exist in some areas, cardiac catheterization units should optimally be located within a facility in which cardiac surgery is performed.

§ 121.209 Radiation therapy.

(a) *Standard.* (1) A megavoltage radiation therapy unit should serve a population of at least 150,000 persons and treat at least 300 cancer cases annually, within three years after initiation.

(2) There should be no additional megavoltage units opened unless each existing megavoltage unit in the health service area(s) is performing at least 6,000 treatments per year.

(3) Adjustments downward may be justified when travel time to an alternate unit is a serious hardship due to geographic remoteness, based on analyses by the HSA.

(b) *Discussion.* While various types of radiation are indicated and used for tumors with different characteristics, megavoltage equipment is accepted as the most efficacious for treatment of deep-seated tumors. Megavoltage equipment is expensive to purchase, install, and support on a continuing basis. Every effort should thus be made to avoid unnecessary duplication of this costly resource. Established standards should provide needed treatment capabilities while preventing unnecessary duplication of radiation therapy units and underutilization of existing capacity. A unit refers to a single megavoltage machine or energy source. The most common types of units to deliver megavoltage therapy are cobalt 60 and linear accelerators. Treatments are meant to be the same as patient visits. A treatment or visit averages 2.2 fields, according to reports from the American College of Radiology. It also reports that about half of new cancer patients require megavoltage radiation therapy, and that many require subsequent courses of treatment. The American College of Radiology has indicated that at least 300 cancer cases annually are a reasonable minimum load for a megavoltage radiation therapy unit in order to maintain an efficient high quality operation. Based on the information and recommendations of the College, as well as comments received from the public and from members of the expert advisory panel which reviewed the standard, the Department has set a minimum standard of at least 300 cancer cases per unit per year. In 1974, the Department commissioned a study of the use of radiation therapy units. A committee appointed by the American College of Radiology and the American Society of Therapeutic Radiology to review that study suggested that economical operation of radiation units would call for existing units to do 5,000-8,700 treatments per year. The 7,500 level was included in the September 23, 1977 NPRM. This target would have required units to treat an average of 30 patients per day. Based on comments received from the profession and the general public, the Department has adjusted the standard downwards to 6,000 treatments per year, an average of about 25 patients per day, to take into account variations in patient mix and work schedules. Since many institutions meet and exceed these targets, this standard in the Department's judgement represents an attainable, efficient level of operation. The indicated target levels are minimal and should generally be exceeded.

Dedicated special purpose and extra high energy machines which have limited but important applications may not perform 6,000 treatments per year and should be evaluated individually by HSAs in the development of Health Systems Plans.

§ 121.210 Computed Tomographic Scanners.

(a) *Standard.* (1) A Computed Tomographic Scanner (head and body) should operate at a minimum of 2,500 medically necessary patient procedures per year, for the second year of its operation and thereafter.

(2) There should be no additional scanners approved unless each existing scanner in the health service area is performing at a rate greater than 2,500 medically necessary patient procedures per year.

(3) There should be no additional scanners approved unless the operators of the proposed equipment will set in place data collection and utilization review systems.

(b) *Discussion.* Because CT scanners are expensive to purchase, maintain and staff, every effort must be made to contain costs while providing an acceptable level of service. Intensive utilization of existing units, regardless of location, will prevent needless duplication and limit unnecessary health care costs. Estimates and surveys for efficient utilization of CT scanners range from 1,800 to over 4,000 patient procedures a year. (One patient procedure includes, during a single visit, the initial scan plus any necessary additional scans of the same anatomic area of diagnostic interest).

The Institute of Medicine, the Office of Technology Assessment and others have carefully reviewed these data and the capabilities of various available units. The Department has reviewed these analyses as well as the extensive literature that has been developed on CT scanners. In arriving at a standard for the use of these machines, the Department has considered a variety of factors, including the difference in time required for head scans and body scans, the need for multiple scans in some patient examinations, variations in patient mix, the special needs of children, time required for maintenance, and staffing requirements. Moreover, the Department considered the actual operating experience of hospitals and institutions reflected in reports on the use of CT scanners.

The standard set in the Department's guidelines is intended to assure effective utilization and reasonable cost for CT scanning. These machines are expensive, and therefore must be used at levels of high efficiency if excessive costs are to be limited. The Department recognizes that the cost of some machines is declining, particularly those that perform only head scans which require less time. For machines that do predominantly head scans, the standard represents an efficient but more easily attainable level of utilization. For scanners capable of performing both head and body scans, it is imperative that they be effectively used in order to spread the high capital expenditures over as much operating time as possible. As the Institute of Medicine report stated, "The high fixed costs of operating a scanner argue for as high a volume of use as the equipment allows without jeopardizing the quality of care."

The Department believes that a 50-55 hour operating week is both consistent with the actual operating experience of many hospitals and a reasonable target. Based on reported experience for the time required for both head scans and body scans, the Department estimated that a patient mix of about 60 percent head scans and about 40 percent body scans, making allowance for the other factors identified above, would allow a CT scanner to perform about 2,500 patient procedures per year if it is efficiently used about 50-55 hours per week. This estimate assumes a higher percent of body scans than is currently being performed. If fewer than 40 percent body scans are performed, then 2,500 patient procedures would involve even less than 50-55 hours per week. Basing the standard on a higher percentage of body scans also takes account of current trends toward increased proportions of such scans.

The Department believes that sharing arrangements in the use of CT scanners is desirable, in line with the national health priorities of section 1502. Individual institutions or providers should not acquire new machines until existing capacity is being well utilized.

In planning for CT scanners, the HSA should take into consideration special circumstances such as: (1) an institution with more than one scanner where the combined average annual number of procedures is greater than 2,500 per scanner although the unit doing primarily body scans is operating at less than 2,500 patient procedures per year; (2) units which are, or will be, devoting a significant portion of time to fixed protocol institutionally approved research projects and (3) units which are, or will be, servicing predominantly seriously sick or pediatric patients. A summary of the data collected on CT scanners should be submitted by the operators to the appropriate HSA to enable it to adequately plan the distribution and use of CT scanners in the area. The data to be collected should include information on utilization and a description of the operations of a utilization review program.

§ 121.211 End-Stage Renal Disease (ESRD).

(a) *Standard.* The Health Systems Plans established by HSAs should be consistent with standards and procedures contained in the DHHS regulations governing conditions for coverage of suppliers of end-stage renal disease services, 20 CFR Part 405, Subpart U.

(b) *Discussion.* The ESRD Program was created pursuant to section 2991 of the Social Security Amendments of 1972 (Pub. L. 92-603), which extends Medicare benefits to any individual who has end-stage renal disease requiring dialysis or transplantation, provided that such individual: (1) is fully or currently insured or entitled to monthly benefits under Title II of the Social Security Act; or (2) is the spouse or dependent child of an individual so insured or entitled to such monthly benefits. In order for an ESRD facility to quality for reimbursement under the program, the facility must meet the conditions for coverage of suppliers of end-stage renal disease services as established by regulation. These conditions incorporate standards which relate to supply, distribution, and organization of ESRD facilities. The standards were developed by the Department of Health and Human Services and were based on extensive consultation with professionals and other persons knowledgeable in the areas of nephrology and transplant surgery. Because these standards are already published as regulations, they are not republished here. The regulations do not try to encourage any particular type of dialysis setting. It is widely recognized that self-care dialysis can significantly contain costs without impairing the quality of care of the suitably chosen patient. The organization of resources to support self-care dialysis is therefore encouraged to the maximum extent practicable.

PART 122—HEALTH SYSTEMS AGENCIES

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AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); sec. 1515 and 1516 of the Public Health Service Act, 88 Stat. 2239, 2241; (41 U.S.C. 300*l*-4, 300*l*-5), unless otherwise noted.

SOURCE: 41 FR 12824, Mar. 26, 1976, unless otherwise noted.

Subpart A—Definitions

§ 122.1 Definitions.

Any terms not defined herein shall have the same meaning as given them in Title XV of the Act.

(a) "Act" means the Public Health Service Act, as amended.

(b) "A-95 Agency" means an areawide planning and development clearinghouse established under Title IV of the Intergovernmental Cooperation Act of 1968.

(c) "Conditionally designated health systems agency" means an entity which has been designated as a health systems agency on a conditional basis pursuant to section 1515(b)(1) of the Act.

(d) "Designation agreement" means an agreement entered into or renewed pursuant to section 1515 of the Act.

(e) "Fully designated health systems agency" means an entity which has been designated as a health systems agency pursuant to section 1515(c)(1) of the Act.

(f) "Governing body" means, in the case of a nonprofit private entity or similar legal mechanism, the governing body of such entity or mechanism and, in the case of a public regional planning body or single unit of general local government, the governing body for health planning of such body or single unit as required by section 1512(b)(3) of the Act which is responsible for the health planning and development functions of such body or single unit.

(g) "Governor" means the chief executive officer of a State or his designee.

(h) "Grant period" means the period with respect to which assistance is provided under Subpart C of this part.

(i) "Health service area" means an area designated by the Secretary pursuant to section 1511 of the Act as a health service area.

(j) "Health systems agency" or "agency" means a conditionally or fully designated health systems agency as defined in paragraphs (c) and (e) of this section.

(k) "Health resources" includes health services, health professions personnel, and health facilities, except that such term does not include Christian Science sanitoriums operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts. For purposes of this subpart, "health professions personnel" means individuals whose main occupation is the delivery of health services.

(l) "Non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget.

(m) "PSRO" means an entity designated as a Professional Standards Review Organization under section 1152 of the Social Security Act.

(n) "Nonprofit", as applied to any entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any private shareholder or individual.

(o) "Provider of health care" means an individual:

(1) Who is a direct provider of health care (including, but not limited to, a physician (doctor of medicine or doctor of osteopathy, dentist, nurse, podiatrist, optometrist or physician assistant in that the individuals' primary current activity is the provision of health care to individuals or the administration of facilities or institutions (including, but not limited to, hospitals, long-term care facilities, substance abuse treatment facilities, out-patient facilities, and health maintenance organizations) in which such care is provided and, when required by State law, the individual has received professional training in the provision of such care or in such administration and is licensed or certified for such provision or administration, or

(2) Who is an indirect provider of health care in that the individual:

(i) Holds a fiduciary position with or has a fiduciary interest in, any entity described in paragraph (o)(2)(ii) (B) or (D) of this section; (for purposes of this paragraph, a "fiduciary position or interest" as applied to any entity means a position or interest with respect to such entity affected with the character of a trust, including members of boards of directors and officers, majority shareholders, agents and attorneys); or

(ii) Receives (either directly or through his spouse) more than one-tenth of his gross annual income from any one or a combination of the following:

(A) Fees or other compensation for research into or instruction in the provision of health care;

(B) Entities or associations or organizations composed of entities or individuals engaged in the provision of health care or in such research or instruction;

(C) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research into or instruction in the provision of health care; and

(D) Entities or associations or organizations composed of entities or individuals engaged in producing drugs or such other articles;

(iii) Is a member of the immediate family of an individual described in paragraph (o)(1) or paragraph (o)(2) (i), (ii), or (iv) of this section (for purposes of this paragraph, "immediate family" as applied to any individual includes only his parents, spouse, children, brothers and sisters who reside in the same household); or

(iv) Is engaged in issuing any policy or contract of individual or group health insurance or hospital or medical service benefits.

(p) "Jurisdiction", as applied to any unit of general local government, means the geographical area within which such unit exercises general purpose political authority.

(q) "Unit of general local government" means (1) any city, municipality, county, township, town, borough, parish, village or other general purpose subdivision of a State; (2) a recognized Indian tribal government; or (3) an Alaska Native Village as defined in the Alaska Native Claims Settlement Act.

(r) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(s) "State" means any one of the several States, the District of Columbia and the Commonwealth of Puerto Rico.

(t) "Statewide health coordinating council" or "SHCC" means the body established pursuant to section 1524 of the Act to advise the State health planning and development agency.

(u) "State health planning and development agency" or "State Agency" means an agency of State government selected by the Governor and designated in an agreement entered into pursuant to section 1521 of the Act to carry out the State's health planning and development program.

[41 FR 12824, Mar. 26, 1976, as amended at 43 FR 1253, Jan. 6, 1978]

Subpart B—Designation of Health Systems Agencies

§ 122.101 Purpose and scope.

(a) Section 1515 of the Public Health Service Act authorizes the Secretary to enter into agreements with eligible entities for the designation of such entities as health systems agencies for health service areas established pursuant to section 1511 of the Act as geographical regions appropriate for the effective planning and development of physical and mental health services. Each such health systems agency shall have as its primary responsibility the provision of effective health planning for its health service area and the promotion of the development within the area of health services, manpower, and facilities which meet identified needs, reduce documented inefficiencies, and implement the health plans of the agency.

(b) The regulations of this subpart are applicable to agreements, pursuant to section 1515 of the Public Health Service Act, under which the Secretary conditionally or fully designates an entity as a health systems agency for a health service area.

§ 122.102 Eligibility.

To be eligible to enter into an agreement under section 1515 of the Act for designation as a health systems agency for a health service area, an entity must be:

(a) A nonprofit private corporation (or similar legal mechanism such as a public benefit corporation) which is incorporated in the State in which the largest part of the population of the health service area resides. Such corporation may not be a subsidiary of, or be otherwise controlled by, any other private or public corporation or other legal entity. For purposes of this subpart, a corporation or similar legal mechanism is controlled by another private or public corporation or other legal entity where such corporation or entity is legally empowered to exercise authority over its performance of the health planning and development functions. Such corporation or similar legal mechanism must be authorized only to engage in health planning and development functions and may not provide health services except for providing (directly or indirectly) health care for its employees.

(b) A single or multipurpose public regional planning body whose planning area is identical to the health service area, and which (1) has a governing board composed of a majority of elected officials of units of general local government or (2) was, prior to January 4, 1975, in existence and authorized by State law to carry out health planning and review functions such as those described in section 1513 of the Act; *Provided however,* That such public regional planning body may not be an agency of state government; or

(c) A single unit of general local government if the area of the jurisdiction of that unit is identical to the health service area.

Provided, That a health systems agency may not be an educational institution or operate such an institution. For purposes of this subpart, (1) an educational institution means an institution whose primary purpose is the provision of educational programs, and (2) an entity shall be deemed to operate such an institution where it has the direct responsibility for administering an educational institution or supervising its administration.

§ 122.103 Application.

An application under this subpart shall be submitted at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the Act, the regulations of this subpart, and any additional terms or conditions of the agreement entered into pursuant to § 122.106 or § 122.107 of this subpart.[1]

§ 122.104 Contents of applications.

In addition to such other information as the Secretary may require, an approvable application shall contain:

(a) In the case of an application for conditional designation pursuant to section 1515(b) of the Act and this subpart:

(1) A copy of the Articles of Incorporation and by-laws of the applicant (or, in the case of a public regional planning body or single unit of general local government, its charter, authorizing statute, ordinance, or executive order and any internal rules or regulations governing its operations) which must meet the requirements of § 122.104(b)(1) of this subpart or, if the entity is not incorporated (or, in the case of a public regional planning body or single unit of general local government, is not chartered or otherwise authorized by statute, ordinance, or executive order) or does not have by-laws (or, with respect to a public regional planning body or single unit of general local government, has not adopted rules or regulations governing its operations) at the time of application, a description of the proposed articles of incorporation or proposed charter, authorizing statute, ordinance, or executive order and by-laws or proposed rules or regulations and the time-table for obtaining such in-

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[1] Applications and instructions may be obtained at the Regional Offices of the Department of Health and Human Services for the region in which the applicant is located.

corporation or authorization and adopting such by-laws or rules or regulations governing its operations) prior to entering into an agreement pursuant to § 122.106 of this subpart.

(2) A description of the health care needs and resources within the health service area.

(3) A detailed description of the functions which the applicant proposes to carry out during the period of the Conditional Designation Agreement, the manner in which it proposes to carry out such functions, and a time-phased plan for the orderly assumption of all the responsibilities and functions of a health systems agency as set forth in section 1513 of the Act (hereinafter referred to as the "work program").

(4) In the case of an applicant which has decided to establish subarea advisory councils, a detailed description of the need for and proposed use of such subarea advisory councils.

(5) A detailed description of the current and projected staff to be employed by the applicant during the period of the conditional designation agreement, including their qualifications (including proposed qualifications where positions are not filled), authority, functions, numbers, assignments, and the manner in which they will be organized to carry out the agency's work program.

(6) A detailed description of the services and the approximate cost of the services the applicant expects to be provided by contractors and consultants.

(7) A detailed description of the facilities, equipment, financial, and other resources available to the applicant.

(8) A detailed description of the manner in which the residents of the health service area have been involved in the formation of the applicant entity and the submission of the application under this subpart including evidence that the applicant has provided at a minimum an opportunity for members of the public to express their views on the qualifications, proposed governing body composition, and proposed work program of the applicant both in writing and at a public meeting sponsored by the applicant entity. Notice of the time, place, and purpose of such meeting shall be given to members of the public through publication of a notice in at least two newspapers of general circulation throughout the health service area at least two weeks prior to such meeting and at least 30 days prior to the date of submission of the application to the Secretary; *Provided*, That effective with respect to entities submitting applications after September 30, 1976, such meeting must be held at least 30 days prior to the date of the submission of the application to the Secretary. Such notice shall also provide that a statement of the qualifications and proposed governing body composition of the applicant and a copy of the proposed work program will be available for public inspection and copying at a specified address, and shall invite written comments thereon by members of the public. A summary of the comments made by the public meetings and copies of any written comments of members of the public shall be appended to the application.

(9) In the case of a nonprofit private applicant, a detailed description of the manner in which local public officials, including representatives of units of general local government or groups of such units, have been involved in the formation of the applicant entity and the submission of the application. Copies of any written comments of such officials shall be appended to the application.

(10) A list of the proposed members of the applicant's governing body and executive committee, if any, including their names, occupations, affiliations, the basis for their membership on the governing body in light of the requirements of section 1512(b)(3)(C) of the Act and § 122.109 of this subpart, and the method utilized in selecting such members.

(11) In the case of an applicant entity which is a public regional planning body or single unit of general local government, a detailed description of the manner in which its governing body will operate, consistent with § 122.109 of this subpart, in carrying out the responsibilities and functions of a health systems agency as set

forth in section 1513 of the Act and this subpart.

(12) Assurances satisfactory to the Secretary that upon completion of the period of conditional designation the applicant will meet all the requirements of section 1512(b) of the Act and be qualified to perform all of the functions prescribed by section 1513 of the Act.

(b) In the case of an application for full designation pursuant to section 1515(c) of the Act and this subpart:

(1) A copy of the Articles of Incorporation and by-laws (or, in the case of a public regional planning body or single unit of general local government, its charter, authorizing statute, ordinance, or executive order, and any internal rules or regulations which govern its operations) of the applicant, which must provide:

(i) That the applicant has the authority to carry out all the responsibilities and functions of a health systems agency as provided in section 1513 of the Act and this subpart;

(ii) That in the case of a private entity, it is nonprofit;

(iii) The manner in which governing body members will be selected and replaced, including provisions for:

(A) Removal of governing body members for good cause only;

(B) Replacement of members in the event of resignation, death, or removal;

(C) Length of terms of members, which may not exceed three years.

(iv) The manner in which the governing body will carry out its responsibilities, including provisions for voting and quorums;

(v) The manner in which the executive committee and subcommittees or advisory groups, if any, will be selected consistent with section 1512(b)(3) of the Act, their responsibilities, and the manner in which they will carry out those responsibilities;

(vi) The manner in which subarea advisory councils, if any, will be established, their members nominated, a description of their functions, and the manner in which they will carry out those functions;

(vii) The manner in which health systems agency representatives to the Statewide Health Coordinating Council will be nominated;

(viii) The manner in which the public will be given adequate notice of business meetings of the agency, which at a minimum must provide for periodic publication in two newspapers of general circulation throughout the health service area of a schedule of the regular meetings of the agency and the address where specific agenda information may be obtained in advance of such meetings; and

(ix) Requirements relating to conflicts of interest which shall be designed to preclude the use of membership on the governing body, the executive committee, if any, or any other subcommittee or advisory group (including subarea advisory councils) for purposes which are, or give the appearance of being, motivated by private gain on the part of any individual.

(2) A detailed description of the manner in which the applicant has met its responsibilities during any prior period of designation under section 1515(b)(1) or 1515(c)(1) of the Act.

(3) A detailed description of the current and projected staff to be employed by the applicant during the period of the designation agreement, including their qualifications (including, proposed qualifications where positions are not filled), authority, functions, numbers, assignments, and the manner in which they will be organized to carry out the functions of the agency.

(4) A detailed description of the services and the approximate costs of the services the applicant expects to be provided by contractors and consultants.

(5) A list of the members of the applicant's governing body and executive committee, if any, including their names, occupations, affiliations, the basis for their membership on the governing body in light of the requirements of section 1512(b)(3)(C) of the Act and § 122.109 of this subpart, and the method utilized in selecting such members.

(6) A detailed description of the facilities, equipment, financial, and

other resources available to the applicant.

(7) A detailed description of the manner in which the community has been involved in the submission of the application under this subpart, including evidence that the applicant has provided at a minimum an opportunity for members of the public to express their views on the qualifications, proposed governing body composition, and proposed application of the applicant both in writing and at a public meeting sponsored by the applicant entity. Notice of the time, place and purpose of such meeting shall be given to members of the public through publication of a notice in at least two newspapers of general circulation throughout the health service area at least two weeks prior to such meeting. Such meeting must be held at least 30 days prior to the submission of the application to the Secretary. Such notice shall also provide that a statement of the qualifications and proposed governing body composition of the applicant and a copy of the proposed application will be available for public inspection and copying at a specified address, and shall invite written comments thereon by members of the public. A summary of the comments made at the public meeting and copies of any written comments shall be appended to the application.

(8) In the case of private nonprofit applicant entities, a detailed description of the manner in which local public officials, including representatives of units of general local government or groups of such units, have been involved in the submission of the application. Copies of any written comments of such officials shall be appended to the application.

(9) A projected work program setting forth the manner in which the applicant proposes to carry out the responsibilities and functions of a health systems agency as set forth in section 1513 of the Act and this subpart.

(10) In the case of an applicant entity which is a public regional planning body or single unit of general local government, a detailed description of the manner in which its governing body will operate, consistent with § 122.109 of this subpart, in carrying out the responsibilities and functions of a health systems agency as set forth in section 1513 of the Act and this subpart.

(11) Assurances satisfactory to the Secretary that the applicant meets and will continue to meet the requirements of section 1512(b) of the Act and is qualified to perform or is performing the functions prescribed by section 1513 of the Act and this subpart.

[41 FR 12824, Mar. 26, 1976, as amended at 47 FR 28652, July 1, 1982]

§ 122.105 Selection of agencies.

(a) *Conditionally designated agencies.* (1) The Secretary, after consultation with and consideration of the recommendations of the appropriate Governor in accordance with paragraph (a)(2) of this section, may enter into a Conditional Designation Agreement with an entity whose designation will, in his judgment, best promote the purpose of section 1513 of the Act and this subpart, taking into consideration among other pertinent factors:

(i) The adequacy of the proposed work program for orderly agency development to meet the requirements for full designation after the period of conditional designation,

(ii) The reasonableness of the proposed work program in light of the financial resources to be available to the applicant,

(iii) The adequacy of the governing body selection procedures in assuring that all affected groups in the health service area had reasonable opportunity to be represented on the governing body;

(iv) The extent and type of involvement of health service area residents in development of the application for designation specifically evidence that the public meeting required by § 122.104(a)(8) of this subpart was widely publicized and that comments made were taken into consideration by the applicant;

(v) The extent of the knowledge within the applicant organization of the needs and resources within the health service area,

(vi) The adequacy of plans for developing working relationships with appropriate A-95 agencies, PSRO's, State Agencies and Statewide Health Coordinating Councils; with health systems agencies which are designated for health service areas within the same standard metropolitan statistical area (as determined by the Office of Management and Budget) as the health service area for which the applicant is seeking designation; and with other planning bodies, and

(vii) The extent to which the application provides for the consideration of special or unique circumstances which affect the application of criteria in paragraph (a)(1) (i) through (vi) of this section, within a State.

Provided, That in considering applications the Secretary shall give priority to an application which has been recommended for approval by each entity which has received a grant under section 314(b) of the Act to develop a plan for all or part of the health service area with respect to which the application was submitted, and by each regional medical program established in such area under Title IX of the Act.

(2) Prior to entering into a Conditional Designation Agreement with an entity with respect to a particular health service area, the Secretary will provide the Governor of each State in which such health service area is located 30 days in which to review and make recommendations concerning such applications for conditional designation. Where the Secretary does not accept such recommendations, he will provide the Governor with a detailed statement of the reasons for the decision. Further, the Secretary will consult with such other State and local officials as he may deem appropriate, and with the SHCC, if any, designated for each State in which the agency's health service area is located, with respect to such designation.

(b) *Fully designated agencies*. (1) The Secretary, after consultation with and consideration of the recommendation of the appropriate Governor in accordance with paragraph (b)(2) of this section, and after conducting a review of the agency's performance during the period of conditional designation, may enter into a Full Designation Agreement with an entity whose performance during such period of conditional designation (which may not be less than one year) and whose application for full designation demonstrate to the satisfaction of the Secretary that it is capable of fulfilling, in a satisfactory manner, the requirements and functions of a health systems agency as provided in sections 1512 and 1513 of the Act and this subpart; *Provided*, That the Secretary will not enter into a Full Designation Agreement with an entity unless such entity has established a health systems plan and annual implementation plan in accordance with section 1513(b) (2) and (3) of the Act and has adopted procedures and criteria required to be utilized pursuant to section 1532 of the Act. In considering applications the Secretary will give priority to an application which has been recommended for designation by each entity which has received a grant under section 314(b) of the Act to develop a plan for all or part of the health service area with respect to which the application was submitted, and by each regional medical program established in such area under Title IX of the Act.

(2) Prior to entering into a Full Designation Agreement with an entity with respect to a particular health service area, the Secretary will provide the Governor of each State in which such health service area is located 30 days in which to review and make recommendations to the Secretary concerning such application for full designation. Where the Secretary does not accept such recommendations he will provide the Governor with a detailed statement of the reasons for the decision. Further, the Secretary will consult with such other State and local officials as he may deem appropriate and with the SHCC, if any, designated for each State in which the agency's health service area is located, with respect to such designation.

[41 FR 12824, Mar. 26, 1976, as amended at 41 FR 31208, July 27, 1976]

§ 122.106 Conditional designation agreements.

In accordance with § 122.105(a) of this subpart, the Secretary may enter into an agreement (hereinafter referred to as the Conditional Designation Agreement) with an entity under which the entity will be designated as a health systems agency on a conditional basis with a view toward determining the entity's ability at the end of the period of its conditional designation to meet the requirements and perform the functions of a fully designated health systems agency under the Act and this subpart. Such agreement shall provide that:

(a) The entity is designated as the conditionally designated health systems agency for a health service area for a term not to exceed 12 months, beginning on a date specified in the agreement.

(b) During the period of conditional designation, the Secretary shall require the agency to meet only such requirements of section 1512(b) of the Act and perform only such of the functions prescribed by section 1513 of the Act and this subpart as he determines such agency to be capable of meeting and performing, and the agency shall perform only those functions under the agreement which the Secretary, in writing, directs it to perform; *Provided,* That the agency must perform at least the functions described in § 122.107(c) (1), (2), (3), (4), (5), (10), (11), (12) and (13) of this part. Where an agency has been unable to enter into any agreement described in § 122.107(c) (10), (11) and (12) within six months from the effective date of the Conditional Designation Agreement, it shall submit at such time a statement indicating the efforts that have been made to secure such agreement, the reason why such agreement has not been entered into and the future actions that the agency proposes to take in order to secure such agreement. Each such agreement shall be designed to take into account the progressive assumption of additional functions by the agency.

(c) During the period of conditional designation the number and types of requirements and functions may, in accordance with paragraph (b) of this section, be progressively increased as the agency, in the judgment of the Secretary, becomes capable of added responsibility: *Provided,* That (1) an agency may not perform the functions described in § 122.107(c) (15) or (17) (except for the review and approval or disapproval of applications for assistance under section 1625 of the Act in accordance with the Appendix to Subpart A of 42 CFR Part 124) during the first year of conditional designation, and may not in any event perform the functions described in § 122.107(c) (15) and (17) (except for the review and approval or disapproval of applications for assistance under section 1625 of the Act) until such agency has established a health systems plan in accordance with section 1513(b) (2) and (3) of the Act and the Secretary has in writing authorized the agency to perform such functions; and (2) an agency may not perform the function described in § 122.107(c)(9) during any period of conditional designation.

(d) The agency shall, during the entire period of the Conditional Designation Agreement, maintain a governing body which meets the requirements of section 1512(b)(3) of the Act and § 122.109 of this subpart.

(e) The agency shall promptly notify the Secretary and the State Agency for each State in which the agency's health service area is located of changes in its legal status, organization, or executive director which occur during the period of the Conditional Designation Agreement.

(f) The agency shall agree to meet the requirements of the Act, this subpart, and any additional conditions set forth in the Conditional Designation Agreements.

[41 FR 12824, Mar. 26, 1976, as amended at 41 FR 31209, July 27, 1976; 42 FR 62270, Dec. 9, 1977]

§ 122.107 Full designation agreements.

In accordance with § 122.105(b) of this subpart, the Secretary may enter into an agreement (hereinafter referred to as the Full Designation Agreement) with an entity under which the entity agrees to perform all the functions of a health systems agency under the Act and this subpart. Such Full Designation Agreement shall provide that:

(a) The entity is designated by the Secretary as a health systems agency for a health service area for a term not to exceed 12 months, beginning on a date specified in the agreement.

(b) The agency shall continue to meet the requirements of section 1515(b)(1) of the Act with respect to legal structure.

(c) The agency shall perform the following functions:

(1) The agency shall assemble and analyze data concerning:

(i) The status (and its determinants) of the health of the residents of the area;

(ii) The status of the health care delivery system in the area and the use of that system by the residents of the area, including patterns of health expenditure and health financing;

(iii) The effect of the area's health care delivery system has on the health of the residents of the area;

(iv) The number, type and location of the area's health services, manpower, and facilities;

(v) The patterns of utilization of the area's health resources; and

(vi) The environmental and occupational exposure factors affecting immediate and long-term health conditions. In carrying out its responsibility to assemble such data, the agency shall coordinate its activities with the cooperative system provided for under section 306(e) of the Act. The agency shall not undertake the collection of data where adequate data is already collected by other entities including those in the cooperative system provided for under section 306(e) of the Act. Where the agency wishes to undertake the design, development and operation of a new data system, whether directly or by the use of contractors or consultants, it must obtain the prior approval of the Secretary. The Secretary will consult with the SHCC, if any, for each State in which the agency's health service area is located concerning such requests for approval.

(2) The agency shall, after appropriate consideration of the recommended national guidelines for health planning policy issued by the Secretary under section 1501 of the Act, the recommendations of the State Agency designated for each State in which the agency's health service area is located concerning measures to meet Statewide health needs, priorities set forth in section 1502 of the Act, and the data developed pursuant to paragraph (1), and in accordance with regulations of the Secretary, establish, annually review, and amend as necessary a health systems plan (hereinafter referred to as the "HSP") which shall be a detailed statement of goals (i) describing a healthful environment and health systems in the area which, when developed, will assure that quality health services will be available and accessible in a manner which assures continuity of care, at reasonable cost, for all residents of the area; (ii) which are responsive to the unique needs and resources of the area; and (iii) which take into account and are consistent with the national guidelines for health planning policy issued by the Secretary under section 1501 of the Act respecting supply, distribution, and organization of health resources and services. Before establishing an HSP, the agency shall conduct a public hearing on the proposed HSP and shall give interested persons an opportunity to submit their views orally and in writing. Not less than 30 days prior to such hearing, the agency shall publish in at least two newspapers of general circulation throughout its health service area a notice of its consideration of the proposed HSP, the time and place of the hearing, the place at which interested persons may consult the HSP in advance of the hearing and the place and period during which to submit written comments to the agency concerning the HSP. After the HSP has been established, the agency shall distribute copies of the HSP to all public libraries in the health service area and shall publish in accordance with the requirements of this paragraph a notice stating that the HSP has been adopted and that the HSP is available at specified addresses for inspection and copying by interested persons.

(3) The agency shall, in accordance with regulations of the Secretary, establish, annually review, and amend as necessary an annual implementation plan (hereinafter referred to as the "AIP") which describes objectives which will achieve the goals of the HSP and priorities among the objec-

tives. In establishing the AIP, the agency shall give priority to those objectives which will maximally improve the health of the residents of the area, as determined on the basis of the relation of the cost of attaining such objectives to their benefits, and which are fitted to the special needs of the area. After the AIP has been established the agency shall distribute copies of the AIP to all public libraries in the health service area and publish in at least two newspapers of general circulation throughout its health service area a notice stating that an AIP has been adopted and that the AIP is available at specified addresses for inspection and copying by interested persons.

(4) The agency shall annually provide copies of the agency's HSP to the State Agency and Statewide Health Coordinating Council designated for each State in which the agency's health service area is located in accordance with their requirements, for integration into the State health plan pursuant to sections 1523(a)(2) and 1524(c)(2)(A) of the Act. As required by the SHCC, the agency shall revise its HSP to achieve appropriate coordination with the HSPs of other health systems agencies which participate in the SHCC or to deal more effectively with statewide health needs.

(5) The agency shall provide to the Statewide Health Coordinating Council and the State Agency for each State in which the agency's health service area is located copies of the agency's AIP.

(6) The agency shall develop and publish specific plans and projects for achieving the objectives established in the AIP which shall include specific strategies for the development and implementation of programs and the priority assigned to the plans and projects developed.

(7) The agency shall seek, to the extent practicable, to implement its HSP and AIP with the assistance of individuals and public and private entities in its health service area.

(8) The agency may provide, in accordance with the priorities established in the AIP, technical assistance to individuals and public and private entities for the development of projects and programs which the agency determines are necessary to achieve the health systems described in the HSP, including assistance in meeting the requirements of the agency with respect to reviews of proposed health systems changes in accordance with section 1532 of the Act and applicable regulations of the Secretary.

(9) The agency shall, in accordance with the priorities established in the AIP, make grants to public and nonprofit private entities and enter into contracts with individuals and public and private nonprofit entities to assist them in planning and developing projects and programs which the agency determines are necessary for the achievement of the health systems described in the HSP. Such grants and contracts shall be made from the Area Health Services Development Fund of the agency established with funds provided under grants made under section 1640 of the Act and in accordance with such regulations as the Secretary may prescribe.

(10) The agency shall coordinate its activities and seek to enter into a written agreement with each PSRO whose PSRO area is in whole or in part in the agency's health service area, for the purpose of achieving coordination of their respective activities and which shall contain at a minimum, the following:

(i) Provision for sharing of data and information, such as statistics on patterns of utilization and quality of care, subject to the requirements of section 1166 of the Social Security Act;

(ii) Provision for review and comment by the PSRO on the HSP, AIP, and the criteria adopted by the agency pursuant to section 1532 of the Act, especially with respect to quality of care, utilization of services and facilities, and need for new resources;

(iii) Provision for technical assistance to be made available by the agency to the PSRO and by the PSRO to the agency especially with respect to the development of the HSP, AIP, and the criteria adopted by the agency pursuant to section 1532 of the Act; and

(iv) Provision to assure that actions taken by the PSRO which alter the area's health system will be taken in a manner which is consistent with the HSP and the AIP in effect for the area. Such agreements shall be reviewed periodically and revised as necessary.

(11) The agency shall coordinate its activities and seek to enter into a written agreement with each A-95 Agency whose area of responsibility is in whole or in part in the agency's health service area, for the purpose of achieving coordination of their respective activities and which shall, at a minimum, contain the following:

(i) Provision for organizational and procedural arrangements for coordination of plan development;

(ii) Provision for formal arrangements for review of health and health-related matters subject to review to assure concurrent and complementary actions;

(iii) Provision for technical assistance to be made available by the agency to the A-95 Agency and by the A-95 Agency to the agency;

(iv) Provision to assure that actions taken by the A-95 agency which alter the area's health system will be taken in a manner which is consistent with the HSP and the AIP in effect for the area; and that actions taken by the agency take into consideration the general plans of the A-95 Agency; and

(v) Provision for sharing of data and information needed for planning activities.

Such agreements shall be reviewed periodically and revised as necessary.

(12) Where an agency is designated for a health service area which contains only a portion of a standard metropolitan statistical area (as determined by the Office of Management and Budget), the agency shall cordinate its activities and seek to enter into a written agreement with the other entity or entities which have been designated as the health systems agency or agencies for the remaining portions of the standard metropolitan statistical area, for the purpose of achieving coordination of their respective activities. The agreement shall contain at a minimum the following:

(i) Provision for review and comment on the HSP, AIP, and plans for the use of the Area Health Services Development Fund, when available, by each such health systems agency;

(ii) Provision for organization and procedural arrangements that will result in joint review of projects and policies and exchange of information on activities that have implications throughout the standard metropolitan statistical area.

(iii) Provision for sharing of data and information needed for planning activities. Such agreements shall be reviewed periodically and revised as necessary.

(13) The agency shall coordinate its activities with (i) entities referred to in paragraphs (1) and (2) of section 204(a) of the Demonstration Cities and Metropolitan Development Act of 1966, (ii) regional and local entities the views of which are required to be considered under regulations prescribed under section 403 of the Intergovernmental Cooperation Act of 1968 to carry out section 401(b) of such Act, (iii) other appropriate general or special purpose regional planning or administrative agencies, and (iv) any other appropriate entity in the agency's health service area. Where appropriate, the agency shall secure data for use in the agency's planning and development activities from such entities, provide technical assistance to such entities, and enter into agreements with such entities which will assure that actions taken by such entities which alter the area's health system will be taken in a manner which is consistent with the area's HSP and AIP.

(14) To assist State Agencies in carrying out their functions under paragraphs (4) and (5) of section 1523(a) of the Act, the agency shall review, in accordance with the procedures and criteria established pursuant to section 1532 of the Act and applicable regulations of the Secretary, the need for new institutional health services (as defined for purposes of section 1523(a) (4) and (5) of the Act) proposed to be offered or developed in the health service area of such agency, and make recommendations to the appropriate State Agency respecting such services, in accordance with procedural requirements developed by the State Agency

and pursuant to section 1122 of the Social Security Act.

(15) The agency may review on a periodic basis in accordance with procedures and criteria established pursuant to section 1532 of the Act and applicable regulations of the Secretary (42 CFR Part 122, Subpart G), at least those institutional and home health services which are offered in the health service area of the agency and with respect to which goals have been established in the State health plan and shall make recommendations to the State Agency for each State in which the agency's health service area is located respecting the appropriateness in the area of such services.

(16) The agency shall annually recommend, in accordance with such regulations as the Secretary may prescribe, to the State Agency for each State in which the agency's health service area is located (i) projects for the modernization, construction, and conversion of medical facilities in the entity's health service area which will achieve the HSP and AIP of the health systems agency, and (ii) priorities among such projects.

(17) The agency may review and approve or disapprove, or may review and comment upon, as appropriate, in accordance with procedures and criteria established pursuant to section 1532 of the Act and applicable regulations of the Secretary (42 CFR Part 122, Subpart E) each specified proposed use within its health service area of Federal funds in accordance with section 1513(e) of the Act and applicable regulations of the Secretary.

(18) The agency shall provide each Indian tribe or intertribal Indian organization which is located within its health service area, information respecting the availability of Federal funds in accordance with section 1513(e) of the Act.

(19)(i) The agency may collect annually on a form developed in consultation with the State Agency (or agencies) the rates charged for each of the twenty-five most frequently used hospital services in the State (or States) including the average semiprivate and private room rates.

(ii) Each health systems agency shall make available to the public for inspection and copying (at a reasonable expense to the public) any information supplied to the health systems agency pursuant to this subparagraph in readily understandable language and in a manner designed to facilitate comparisons among the hospitals in the health systems agency's health service area.

(d) The agency shall maintain a staff which meets the requirements of section 1512(b)(2) of the Act and § 122.110 of this subpart.

(e) The agency shall, during the entire period of the Full Designation Agreement, maintain a governing body which meets the requirements of section 1512(b)(3) of the Act and § 122.109 of this subpart.

(f) The agency shall promptly notify the Secretary and the State Agency for each State in which the agency's health service area is located of changes in its legal status, organization, or executive director which occur during the period of the Full Designation Agreement.

(g) The agency agrees to meet the requirements of the Act, this subpart, and any additional conditions set forth in the Full Designation Agreement.

[41 FR 12824, Mar. 26, 1976, as amended at 47 FR 3552, Jan. 26, 1982]

§ 122.108 Renewal and termination of agreements.

(a) *Conditionally designated agencies*—(1) *Renewal.* A Conditional Designation Agreement may, at the option of the Secretary and based upon the Secretary's review of the agency's performance during its period of conditional designation, its application for renewal, and after consultation with the Governor and the SHCC for each State in which the agency's health service area is located, be renewed for an additional term not to exceed 12 months, but in no case may the total period of conditional designation of an agency exceed 24 months. Where the Secretary determines not to renew such agreement, the agency will be notified in writing of the reasons for such determination.

(2) *Termination.* A Conditional Designation Agreement may be terminat-

ed by the agency prior to the expiration of its term upon 90 days written notice to the Secretary which shall set forth the reasons for such termination and its effective date. The Secretary may terminate the Conditional Designation Agreement prior to the expiration of its term upon his determination, after having given the agency at least 90 days written notice of its deficiencies and the corrective actions required and an opportunity for a hearing before an officer or employee of the Department designated for such purpose by the Secretary, that the agency is not complying with the provisions of the Agreement or is incapable of progressively assuming more functions and responsibilities. The Secretary will consult with the Governor and the SHCC for each State in which the agency's health service area is located concerning any proposed termination.

(b) *Fully designated agencies*—(1) *Renewal.* A Full Designation Agreement may be renewed for a period not to exceed 12 months, upon the application by the agency for renewal, if upon review by the Secretary (as provided in section 1535 of the Act) and after consultation with the Governor and the SHCC for each State in which the agency's health service area is located, he determines that it has fulfilled, in a satisfactory manner, the functions of a health systems agency as prescribed by section 1513 of the Act and the applicable provisions of this subpart and continues to meet the requirements of section 1512(b) of the Act. A determination by the Secretary not to renew the Agreement will be made only after he has provided the agency with written notice of the reasons for such failure to renew and the opportunity for a hearing before an officer or employee designated for such purpose by the Secretary.

(2) *Termination.* A Full Designation Agreement may be terminated by the agency prior to the expiration of its term upon 90 days written notice to the Secretary which will set forth the reasons for such termination and its effective date. The Agreement may be terminated by the Secretary prior to the expiration of its term if he determines, after having given the agency at least 90 days notice of its deficiencies and the corrective actions required and an opportunity for a hearing before an officer or employee of the Department designated for such purpose by the Secretary, that the agency is not complying with or effectively carrying out the provisions of the Agreement. The Secretary will consult with the Governor and the SHCC for each State in which the agency's health service area is located concerning any proposed termination.

§ 122.109 Governing body; executive and other committees.

(a) *General.* (1) A health systems agency which is a public regional planning body or single unit of general local government shall have, in addition to any other governing board, a governing body for health planning (hereinafter referred to as the "governing body") which is established in accordance with the requirements in paragraphs (b) and (c) of this section and which has the responsibilities prescribed by paragraph (d) of this section.

(2) A health systems agency which is a non-profit private corporation (or similar legal mechanism) shall have a governing body to direct all its health planning and development activities which is established in accordance with the requirements in paragraphs (b) and (c) of this section.

(b) *Composition.* The membership of the governing body of an agency shall meet the following requirements:

(1) *Consumer composition requirements.* A majority (but not more than 60 per centum) of the members shall be residents of the health service area served by the agency who are consumers of health care and who are not providers of health care, and who are broadly representative of the health service area. The consumer majority must include individuals representing the principal social, economic, linguistic, handicapped, and racial populations and geographic areas of the health service area and major purchasers of health care in the area.

(i) The purpose of the requirements of this subparagraph is to ensure that each health systems agency will be governed by a body with a consumer majority which, looked at as a whole, includes and may reasonably be expected to consider and articulate the interests of all segments of the population of its health service area in carrying out its health planning functions. Accordingly, while no specific quotas or percentages of representation are required, the Secretary must be satisfied that the consumer majority of the governing body is broadly representative of the entire population of the area. In particular, the following groups must be represented on the consumer majority:

(A) Each identifiable racial or linguistic population group which constitutes at least ten percent of the population of the area;

(B) Lower, middle and upper income economic groups;

(C) Women;

(D) Persons age 65 and over; and

(E) The handicapped, as that term is defined in Section 504 of the Rehabilitation Act of 1973 (see also paragraph (b)(3)(iv) of this section).

(ii) In order to be considered a representative of a specific population group, an individual must either be a member of that group or have been selected as a representative by an organization composed primarily of members of that group.

(iii) For purposes of this paragraph, "major purchaser of health care" means an entity (including a labor organization or a business corporation), other than an entity described in paragraph (b)(2) of this section, which either directly or indirectly (such as through the purchase of group health insurance or hospital or medical service benefits) provides health care for its employees, members, or beneficiaries.

(2) *Provider composition requirements.* The remainder of the members shall be residents of, or individuals whose principal place of business is in, the health service area served by the agency who are providers of health care and who represent:

(i) Physicians (particularly practicing physicians), dentists, nurses, optometrists, podiatrists, physician assistants, and other health professionals;

(ii) Health care institutions (particularly hospitals, long-term care facilities, rehabilitation facilities, alcohol and drug abuse treatment facilities, and health maintenance organizations);

(iii) Health care insurers;

(iv) Health professional schools (which include schools of medicine, dentistry, osteopathy, optometry, podiatry, pharmacy and veterinary medicine as defined in section 724(4) of the Act, and schools of nursing as defined in section 853 of the Act);

(v) The allied health professions; and

(vi) Other providers of health care.

At least one-half of the providers of health care who are members of the governing body shall be direct providers of health care, at least one of whom must be a person engaged in the administration of a hospital.

(3) *Miscellaneous composition requirements.* The total membership as described in paragraphs (b)(1) and (b)(2) of this section shall:

(i) Include (either through consumer or provider members) at least one public elected official and at least one other representative of a unit of general purpose local government in the agency's health service area. To be considered a representative of a unit of general purpose local government, an individual must be appointed by that unit or a combination of such units. Where the health service area of the agency includes an entire State, the government of that State shall be deemed to be a unit of general purpose local government for purposes of this subsection;

(ii) Include representatives of public and private agencies in the area concerned with health;

(iii) Include a percentage of individuals who reside in nonmetropolitan areas within the health service area that is at least equal to the percentage of residents of the area who reside in nonmetropolitan areas;

(iv) Include at least one consumer and one provider member who are knowledgeable about mental health services. The requirement of this subsection pertaining to consumer membership and the requirement of paragraph (b)(1)(i)(E) pertaining to representation of the handicapped may not be satisfied by the designation of a single individual to serve in both capacities;

(v) If the agency serves an area in which there is located one or more hospitals or other health care facilities of the Veterans Administration, include, as a nonvoting, ex officio member, an individual whom the Chief Medical Director of the Veterans Administration shall have designated for that purpose. A member appointed under this subsection shall not be considered in determining the number of members of the governing body for purposes of the numerical limits prescribed by paragraph (c) of this section; and

(vi) If the agency serves a health service area in which there is located one or more health maintenance organizations, include at least one member who is representative of such organizations. For purposes of this subsection, a health maintenance organization shall be considered to be "located in" a health service area if (A) more of the HMO's enrollees reside in the area than in any other health service area, or (B) a health service delivery facility owned or operated by the organization is located in the area, or (C) a substantial number of area residents are enrollees of a health maintenance organization, or (D) a number of physicians are providing health care services to HMO members in the health service area through an independent practice association model health maintenance organization.

(c) *Number of members.* The governing body shall be composed of not less than 10 members nor more than 30 members, except that the number of members may exceed 30 where the governing body has, in accordance with its Articles of Incorporation or by-laws (or in the case of a public regional planning body or single unit of general local government, its charter, authorizing statute, ordinance, or executive order, or any rules or regulations governing its internal management), established an executive committee which meets the requirements of paragraph (f)(1) of this section.

(d) *Responsibilities and authority.* (1) The governing body of a health systems agency shall:

(i) Be responsible for the internal affairs of the agency, including matters relating to the staff of the agency and the agency's budget;

(ii) Be responsible for the adoption of procedures and criteria developed and published pursuant to section 1532 of the Act and applicable regulations of the Secretary to be utilized in the agency's performance of its functions under section 1513(e), (f) and (g) of the Act;

(iii) Be responsible for issuing an annual report concerning the activities of the agency in accordance with § 122.115 of this subpart; and

(iv) Have the exclusive authority to perform for the agency the functions described in section 1513 of the Act and the agency's designation agreement entered into pursuant to § 122.106 or 122.107 of this subpart. For such purposes the term "exclusive" as it applies to the role of the governing body means that the governing body shall have the sole, undivided authority to act for the agency in performing such functions subject to the provision of paragraph (f)(1) of this section relating to the delegation of functions to an executive committee; *Provided,* That this does not preclude the public regional planning body or single unit of general local government from establishing procedures not inconsistent with the requirements of this part for the functioning of the agency, including an opportunity to comment on any action proposed by the governing body in the performance of its functions; and *Provided further,* That the public regional planning body or single unit of general local government must be given the opportunity to comment on the health systems plan and the annual implementation plan prior to their establishment.

(2) The public regional planning body or single unit of general local government may establish rules and regulations for the exercise of the responsibilities described in paragraph (d)(1) of this section by the governing body; *Provided,* That such rules and regulations are not inconsistent with

the Act and the regulations of this part.

(e) *Meetings and conduct of business.* The governing body shall:

(1) Meet at least once in each calendar quarter of a year and at least two additional times in a year unless its executive committee, if any, meets at least twice in that year;

(2) Act only by vote of a majority of its members present and voting at a meeting called upon adequate notice to all its members and at which a quorum, which shall be not less than one-half of its members, is in attendance;

(3) Conduct its business meetings in public, give adequate notice to the public of such meetings (as required by the agency's Articles of Incorporation or by-laws or, in the case of a public entity, its charter, authorizing statute, ordinance, or executive order or any rules or regulations for internal management) and make its data and records available to the public in accordance with the requirements of § 122.114 of this subpart; For purposes of this subpart, "business meetings" are meetings at which the governing body formally acts to carry out its responsibilities and functions under the Act, and

(4) Reimburse its members for their reasonable costs incurred in attending meetings of the governing body.

(f) *Executive committee, subcommittees, and advisory groups*—(1) *Executive committee.* (i) A governing body whose membership exceeds 30 shall establish an executive committee of its members, which shall consist of not more than 25 members, shall be composed in accordance with the requirements of paragraph (b) of this section, and shall be delegated the authority to take such action as the governing body is authorized to take (other than authority to take action with respect to the agency's articles of incorporation or by-laws or in the case of an agency which is a public regional planning body or single unit of general local government its charter, authorizing statute, ordinance, or executive order and any internal rules or regulations which govern its operations) except that the executive committee may not be delegated the responsibility for the establishment and amendment of the health systems plan and annual implementation plan required by section 1513(b) (2) and (3) of the Act.

(ii) The executive committee shall (A) act only by vote of a majority of its members present and voting at a meeting called upon adequate notice to all of its members at which a quorum, which shall be not less than ½ of its members, is in attendance, and (B) conduct its business meetings in public, give adequate notice to the public of such meetings (as required by the agency's Articles of Incorporation or by-laws or, in the case of a public regional planning body or single unit of general local government, its charter, authorizing statute, ordinance, or executive order or any rules or regulations for internal management) and make its data and records available to the public in accordance with the requirements of § 122.114 of this subpart.

(2) *Subcommittees and advisory groups.* Where in the exercise of its functions the governing body or executive committee appoints a subcommittee of its members or an advisory group, it shall, to the extent practicable, make its appointments to such subcommittee or group in such a manner as to provide that the representation on such subcommittee or group meets the composition requirements of paragraph (b) of this section.

[41 FR 12824, Mar. 26, 1976, as amended at 43 FR 1253, Jan. 6, 1978; 47 FR 28651, July 1, 1982]

§ 122.110 Health systems agency staff.

(a) A fully designated health systems agency must have a staff of adequate numbers and appropriate skills, as described in paragraph (b) of this section, to carry out the functions of the agency as described in section 1513 of the Act; *Provided,* That an agency must have a staff numbering not less than five professional members or one professional member for every 100,000 population as determined in accordance with § 122.205 of this part, whichever is greater up to a maximum of 25; and *Provided further,* That the staff shall include and shall be headed by a full time executive director who is responsible for the organization and management of the staff.

(b) The staff of the agency shall provide the agency with expertise in at least the following: (1) Administration, (2) the gathering and analysis of data, (3) health planning, and (4) development and use of health resources. The staff shall be organized in such a fashion that the functions of planning and of development of health resources shall be conducted by staffs with skills appropriate to each function.

(c) The staff of the agency shall be selected, paid, promoted, and discharged in accordance with such personnel system as the agency may establish, except that the rate of pay for any position shall not be less than the rate of pay prevailing in the health service area for similar positions in public or private health service entities.

§ 122.111 Contracting for services; consultants.

(a) If necessary for the performance of its functions, and subject to the requirements of paragraphs (b) and (c) of this section, a health systems agency may employ consultants and may contract with individuals and entities for the provision of services.

(b) A health systems agency which employs consultants to assist the agency in the performance of its functions must adopt and follow a uniform policy for the employment of consultants which requires, at a minimum, a written finding by the agency prior to the employment of each consultant that:

(1) The consultant services to be provided are essential to the performance of the agency's function and cannot be performed by persons otherwise presently employed by the agency;

(2) A selection process for consultants has been employed to assure the selection of the most qualified individual available;

(3) The selection of the consultant has been approved by the executive director of the agency; and

(4) The payment to the consultant is appropriate considering the individual's qualifications, normal charges for similar services, and the nature of the services rendered.

Provided, That a member of an agency's governing body may not be employed by that agency as a paid consultant.

(c) A health systems agency may contract with other entities to assist the agency in the performance of specific administrative support activities such as payroll, accounting, and computer services. The agency may also contract with other entities to provide it with assistance in the performance of the functions assigned to the agency in its designation agreement, except that the agency may not contract for the performance of an entire function for it by another entity; *Provided*, That the agency has made a written finding that the contract services are essential to the performance of the agency's functions, and cannot be provided by persons otherwise employed by the agency; and *Provided further*, That an agency may not contract for the performance of routine staffing and planning functions.

§ 122.112 Subarea advisory councils.

(a) A health systems agency may establish subarea advisory councils representing parts of the agency's health service area to advise the agency on the performance of its functions. The composition of such council must conform to the requirements of section 1512(b)(3)(C) of the Act as applied to that part of the agency's health service area which the subarea advisory council represents.

(b) Consistent with the provisions of § 122.111(c) of this subpart, a health systems agency may make financial and other resources available to the subarea advisory council to assist it in performing agreed upon activities which the agency has requested such council to perform. Such activities may include making recommendations to the agency (1) to assist it in obtaining local or regional advice on the performance of its functions, (2) with regard to proposed membership on the governing body and advisory groups and (3) with regard to planning needs for the local area.

§ 122.113 Private funds, services, or facilities.

(a) No health systems agency (whether conditionally or fully designated) may accept any funds or contributions of services or facilities from any individual or private entity which has a financial, fiduciary, or other direct interest in the development, expansion, or support of health resources, unless in the case of an entity, it is an organization described in section 509(a) of the Internal Revenue Code of 1954 and is not directly engaged in the provision of health care in the health service area of the agency. The prohibition of this section includes contributions of cash, bonds and other securities, services, property, or equipment as well as payments made to the agency under contracts, grants, or loans; *Provided,* That service on a governing body, executive committee, subcommittee, subarea advisory council or advisory group shall not be deemed to be a contribution of services.

(b) For purposes of this section, an individual or private entity which has a financial, fiduciary, or other direct interest in the development, expansion or support of health resources includes but is not limited to:

(1) With respect to any individual, one who

(i) Is a provider of health care as defined in § 122.1(o) of this part;

(ii) Is an employee of any entity described in paragraph (b)(2) of this section; or

(iii) Holds a fiduciary position or has a fiduciary interest as defined in § 122.1(o) of this part in any entity described in paragraph (b)(2) of this section.

(2) With respect to any private entity:

(i) Entities and organizations and associations composed of entities engaged in the provision of health care, including hospitals, long-term care facilities, and health maintenance organizations) and organizations and associations of such institutions; *Provided,* That any entity will not be considered a health care institution for purposes of this section solely on the basis of providing (directly or indirectly) health care for its employees;

(ii) Entities and organizations and associations of entities engaged in research into the provision of health care;

(iii) Health professions schools and organizations and associations of such schools;

(iv) Health professions professional societies;

(v) Entities and organizations and associations of entities engaged in issuing any policy or contract of individual or group health insurance or hospital or medical services benefits and associations and organizations of health care insurers;

(vi) Providers of ancillary medical services (including laboratory services, manufacture or sale of medical devices and equipment, and pharmaceutical services);

(vii) Allied health professions training programs;

(viii) Entities producing drugs for individuals or entities for use in the provision of health care or research into or instruction in the provision of health care; and

(ix) Entities which are in a position with respect to the entities listed in this paragraph affected with the character of a trust, including trustees, boards of directors and majority shareholders.

Provided, That private entities which would be included within this paragraph shall not be included if such contribution is being made in connection with the dissolution of the entity in accordance with applicable State law.

§ 122.114 Access of the public to agency records and data.

(a) Each agency shall adopt a policy for making its records and data available to the public for inspection and copying in accordance with section 1512(b)(3)(B) of the Act, which shall include a procedure for the submission of requests to the agency by members of the public, the agency's procedure for handling such requests, and a uniform fee schedule for copying such material which shall be limited to reasonable costs. For purposes of this section, "records and data" includes publications, brochures, pamphlets, punch cards, magnetic tapes, minutes, staff manuals, slides, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by the agency in connection with the performance of the agency's functions under its designation agreement and retained by the agency as evidence of the agency's functions, policies, decisions, procedures, operations, programs, or other activities.

(b) Each agency is required to maintain and make available for public inspection and copying an index of the records and data of the agency and must publish within 3 months of the effective date of its designation agreement, in at least two newspapers of general circulation throughout its health service area, a notice setting forth the policy adopted pursuant to paragraph (a) of this section.

§ 122.115 Annual report.

(a) Each agency shall issue an annual report concerning the activities of the agency which shall include:

(1) The HSP and AIP developed by the agency pursuant to section 1513(b) (2) and (3) of the Act and this subpart, either in their entirety or by incorporation by reference. Where such plans are included by incorporation by reference, the report shall include a summary of the HSP and AIP and a statement of where copies of the HEP and AIP and supporting documentation may be obtained by interested persons;

(2) A detailed description of the agency's progress in meeting the objectives of its work program during the past year;

(3) A list of the agency's income, expenses, assets, and liabilities, including a list of all contributors to the agency; and

(4) A list of the members of the agency's governing body, executive committee, if any, and staff.

(b) Such report shall be made available at no cost upon request to the residents of the health service area served by the agency and shall be distributed to all public libraries throughout the health service area, to the State Agency for each State in which the agency's health service area is located, and to all newspapers, radio stations and television stations serving the population of the health service area. Notice of the availability of the annual report shall appear in at least two newspapers of general circulation throughout the health service area.

Subpart C—Grants to Health Systems Agencies

§ 122.201 Applicability.

The regulations of this subpart are applicable to grants under section 1516 of the Public Health Service Act (42 U.S.C. 300*l*-5) to health systems agencies designated under section 1515 of the Public Health Service Act (42 U.S.C. 300*l*-4) to assist in meeting the cost of compensation for health systems agency personnel, collection of data, planning, and the performance of the functions of the health systems agency.

§ 122.202 Eligibility.

Any conditionally or fully designated health systems agency is eligible for a grant under this subpart.

§ 122.203 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe and shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart, and any additional terms or conditions of the grant.[1] A copy of such application shall at that time also be submitted to the SHCC, if any, for each State in which the agency's health service area is located.

(b) The application shall contain the following:

(1) A detailed budget for the grant period;

(2) A statement and justification of the amount of grant funds requested; and

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[1] Applications and instructions may be obtained at the Regional Office of the Department of Health and Human Services for the region in which the health systems agency is located.

(3) Where the applicant is requesting an increased amount of grant funds pursuant to section 1516(b)(2) of the Act and § 122.204 of this subpart based on its assurance of providing non-Federal funds to be expended or obligated during the grant period, the application shall also contain:

(i) A total dollar figure of the amount of non-Federal funds meeting the requirements of § 122.206 of this subpart that the applicant assures will be expended or obligated during the grant period for the purposes for which funds awarded under this subpart may be expended or obligated, and

(ii) A statement of the dollar figure of the amount of non-Federal funds which the applicant has currently available and a detailed timetable for the applicant's receipt of the remainder of the funds assured, including documentary evidence concerning the sources and amounts of the proposed contributions, such as letters of intent to contribute specific amounts of funds.

§ 122.204 Grant award.

(a) The Secretary will after considering any recommendations made by the SHCC, if any, for each State in which the agency's health service area is located award a grant under this subpart to each health systems agency whose application meets the applicable requirements of the Act and this subpart.

(b) The amount of any grant under the subpart shall be an amount determined by the Secretary in accordance with the formula set forth in section 1516(b) (1) and (2) of the Act, except that no such grant may be less than $175,000; *Provided*, That (1) If the total of the amount so computed for any fiscal year exceeds the total of the amounts appropriated for such grants in such year, the amount of the grant for that fiscal year to each agency shall be the greater of:

(i) An amount which bears the same ratio to the amount so computed for that agency for that fiscal year as the total of the amounts appropriated for such grants for such fiscal year bears to the total of the amounts so computed, reduced by an amount necessary to assure that no grant will be less than $175,000, or

(ii) $175,000.

(2) If the amount appropriated for any fiscal year is less than the product of $175,000 times the number of conditionally and fully designated agencies, each fully designated agency shall receive $175,000 and each conditionally designated agency shall receive an equal share of the remainder of the funds appropriated.

(3) If the amount appropriated for any fiscal year is less than the product of $175,000 times the number of fully designated agencies, each fully designated agency shall receive an equal share of the funds appropriated.

(c) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which such funds will be available for obligation in accordance with § 122.208(c) of this subpart.

[41 FR 12824, Mar. 26, 1976, as amended at 42 FR 18279, Apr. 6, 1977]

§ 122.204A Discretionary funding.

In addition to the grant award under § 122.204(a), the Secretary may, under the circumstances set forth below, award a fully designated HSA an amount determined under paragraph (c) of this section to assist it in meeting extraordinary expenses which would not otherwise be covered under the grant award.

(a) *Eligibility.* (1) Any fully designated agency which (i) serves a large geographic health service area, or (ii) whose health service area is located in portions of two or more States, or (iii) serves a health service area with a medically underserved population of at least 25 percent of the population of the area or 250,000 persons, whichever is less, is eligible to apply for additional funds under this subpart to assist in meeting the extraordinary expenses associated with these three characteristics.

(2) For purposes of this paragraph, (i) medically underserved populations will be those designated by the Secretary under 42 CFR 51c.102(e), and (ii) an agency will be considered to serve a large geographic health service area if the area covers (A) 20,000 square miles

or more, or (B) 10,000-19,999 square miles and has a population density of less than 50 persons per square mile.

(b) *Application.* Eligible agencies may apply for these additional funds by submitting PHS Form 5161-1.

(c) *Amount.* The amount of additional funds to be awarded under this section is as follows:

(1) An agency described in paragraph (a)(1)(i) of this section will receive in fiscal year 1980 (i) $15,000 if it serves a health service area which covers 20,000 square miles or more and has a population density of less than 50 persons per square mile; (ii) $7,500 if it serves a health service area which covers 20,000 square miles or more and has a population density of 50 or more persons per square mile, or (iii) $7,500 if it serves a health service area which covers 10,000-19,999 square miles and has a population density of less than 50 persons per square mile, unless the agency requests a lesser amount.

(2) An agency described in paragraph (a)(1)(ii) of this section will receive in fiscal year 1980 $7,500 unless the agency requests a lesser amount.

(3) An agency described in paragraph (a)(1)(iii) of this section will receive in fiscal year 1980 an amount equal to the product of two cents and the medically underserved population of the health service area, unless the agency requests a lesser amount.

[45 FR 59133, Sept. 5, 1980]

§ 122.205 Determination of the population of health service areas.

For purposes of section 1516 of the Act and § 122.204 of this subpart, the population of a health service area will be determined annually by the Secretary on the basis of the latest available estimate from the Department of Commerce. The Secretary shall make available and publish annually in the FEDERAL REGISTER a list of all health service areas and their populations as determined in accordance with this section.

§ 122.206 Assurance of expenditure of non-Federal funds.

(a) In accordance with section 1516 of the Act and § 122.204 of this subpart, an agency may receive an increased amount of grant funds where the agency provides assurance satisfactory to the Secretary that the agency will expend or obligate non-Federal funds during the grant period for the purposes for which grants under this subpart may be made. In determining whether such assurance is satisfactory, the Secretary will take into consideration the agency's past performance in meeting such assurances, and where an agency has previously failed to meet the assurances, the Secretary may require further evidence of the agency's current ability to meet an assurance provided by the agency under this section, including evidence that the agency has the non-Federal funds assured currently available.

(b) The non-Federal funds which an agency may use for the purpose of obtaining an increased amount of grant funds pursuant to section 1516(b)(2) of the act and § 122.204 of this subpart may be any contribution of funds (excluding in-kind contributions) from public or private sources, including State and local general revenue funds, but shall

(1) Not include any funds contributed to any agency by an individual or private entity which has a financial, fiduciary, or other direct interest in the development, expansion, or support of health resources as defined in § 122.113 of this part;

(2) Not be paid to the agency for the performance of particular services by it; and

(3) Be contributed to the agency without conditions as to their use other than the condition that the funds be used for the purposes for which a grant under section 1516 and this subpart may be used.

§ 122.207 Grant payments.

The Secretary will from time to time make payments to a grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the grant period or in advance for expenses to be incurred in the grant period, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved activity.

§ 122.208 Use of grant funds.

(a) Any funds granted pursuant to this subpart, as well as other funds required as a condition of the grant to be used in performance of the approved activity, shall be expended solely for carrying out the approved activity in accordance with section 1516 of the Act, the regulations of this subpart, the terms and conditions of the grant award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Funds granted pursuant to this subpart may be expended for the following purposes:

(1) Compensation of agency personnel;

(2) The performance of the agency's functions as specified in Subpart B of this part;

(3) Employment of consultants to assist the health systems agency in the performance of its functions in accordance with § 122.111 of this part; and

(4) Contracts with other entities in accordance with § 122.111 of this part: *Provided,* That grant funds may not be used to make payments under a grant or contract with another entity for the development or delivery of health services or resources.

(c) Funds granted pursuant to this subpart shall be available for obligation during the period of an agency's designation agreement current at the time of the grant award.

§ 122.209 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80). Nor shall any person be denied employment in or by such program or activity so receiving Federal financial assistance on the ground of sex, age, creed, or marital status.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

(c) Grant funds used for alteration or renovation shall be subject to the condition that the grantee shall comply with the requirement of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

[41 FR 12833, Mar. 26, 1976; 41 FR 23386, June 10, 1976]

§ 122.210 Publications and copyright.

(a) *Local governments.* Where the grantee is a local government as defined in 45 CFR 74.3, the Department of Health and Human Services copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable material developed or resulting from the activity supported by a grant under this subpart.

(b) *Grantees other than local governments.* Where the grantee is not a local government as so defined, except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from an activity supported by a grant under this subpart, subject, however, to a royalty-free, nonexclusive, and irrevocable license in the Department to reproduce, publish, or otherwise use, and to authorize others to use the work for government purposes.

§ 122.211 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart.

(b) *Accounting for non-Federal funds.* Where a health systems agency has received an increased amount of grant funds based on its assurance of expenditure of non-Federal funds, the agency shall account for the sum total of the amount so assured by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures in such amount during the grant period for costs meeting the requirements of this subpart.

(c) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(1) *Local governments.* Where the grantee is a local government as defined in Subpart A or 45 CFR Part 74, royalties shall be accounted for as provided in 45 CFR 74.44.

(2) *Grantee other than local governments.* Where the grantee is not a local government as so defined royalties shall be accounted for as follows:

(i) Patent royalties, whether received during or after the grant period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials, and any royalties in excess of publishing or producing the materials shall be distributed in accordance with Chapter 1-420 of the Department of Health and Human Services Grants Administration Manual.[2]

(d) *Audit.* Where a grantee is a local government as defined in Subpart A of 45 CFR Part 74, audits shall be conducted as provided in 45 CFR 74.61. Where a grantee is not a local government as so defined, it shall arrange for an annual independent financial audit of the approved activity.

§ 122.212 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to local governments as defined in Subpart A of that Part 74. The relevant provisions of the following subparts of 45 CFR Part 74 shall also apply to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:

A	General.
B	Cash Depositories.
C	Bonding and Insurance.
D	Retention and Custodial Requirements for Records.
F	Grant-Related Income.
H	Standards for Grantee and Subgrantee Financial Management Systems.
I	Financial Reporting Requirements.
K	Grant Payment Requirements.
L	Budget Revision Procedures.
M	Grant Close-out, Suspension, and Termination.
O	Property.
P	Procurement Standards.
Q	Cost Principles.

§ 122.213 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

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[2] The Department of Health and Human Services Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Subpart D—Certificate of Need Reviews

AUTHORITY: Section 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sections 1501-1532 of the Public Health Service Act, 93 Stat. 592-630 (42 U.S.C. 300k-1—300n-1).

SOURCE: 45 FR 69742, Oct. 21, 1980, unless otherwise noted.

§ 122.301 Definitions.

Terms used in this subpart shall have the meanings given them in Subpart A of this part and § 123.401 of this title.

§ 122.302 Purpose and applicability.

(a) Section 1513(f) of the Act requires each health systems agency to assist State Agencies in carrying out certificate of need programs under section 1523(a)(4)(B) of the Act. In doing so, health systems agencies are required to review and make recommendations to the appropriate State Agency respecting the need within the health service area for capital expenditures, new institutional health services, and major medical equipment.

(b) Section 1532(a) of the Act requires that in performing its review functions under section 1513(f) of the Act, each health systems agency shall (except to the extent approved by the Secretary) follow procedures and apply criteria developed and published by the health systems agency in accordance with regulations of the Secretary. This subpart sets forth requirements respecting these procedures and criteria.

§ 122.303 General.

Each recommendation by the health systems agency to a State Agency to issue or not to issue a certificate of need or to withdraw a certificate of need must be based solely (a) on the review by the health systems agency conducted in accordance with procedures and criteria it has adopted under this subpart and (b) on the record of the administrative proceedings held on the application for the certificate or the State Agency proposal to withdraw the certificate.

§ 122.304 Scope of certificate of need review programs.

Each health systems agency shall conduct reviews of projects located or proposed to be located within its health service area and which are subject to review under the State certificate of need program under Subpart E of Part 123 of this title.

§ 122.305 Health maintenance organizations (HMOs).

(a) *Inclusion in health plans.* If an HMO or a health care facility which is controlled, directly or indirectly, by an HMO applies for a certificate of need, the health systems agency shall not recommend denial of the certificate of need (or otherwise make a finding under this subpart that the project is not needed) solely because the proposal is not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(b) *Required recommendation to approve.* Notwithstanding general review criteria established in accordance with § 123.412 of this title, if an HMO or a health care facility which is controlled, directly or indirectly, by an HMO applies for a certificate of need, the health systems agency shall recommend issuance of the certificate of need if it finds (in accordance with § 123.412(a)(13) of this title) that

(1) Issuance of the certificate of need is required to meet the needs of the members of the HMO and of the new members which the HMO can reasonably be expected to enroll, and

(2) The HMO is unable to provide, through services or facilities which can reasonably be expected to be available to the HMO, its institutional health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO and which makes these services available on a long-term basis through physicians and other health professionals associated with it.

§ 122.306 Required recommendations.

Under § 123.407 of this title, if an application is made for a certificate of need for a capital expenditure, a certificate of need must be issued if:

(a) The capital expenditure is required to eliminate or prevent safety hazards, or to comply with licensure, certification, or accreditation standards, and

(b) If the State Agency determines (1) that the facility or service for which the capital expenditure is proposed is needed, and (2) that the obligation of the capital expenditure is consistent with the State health plan. For those applications for which approval is sought under § 123.407 of this title, the health systems agency is required to make recommendations to the State Agency on whether the project meets the conditions in § 123.407(a).

EXPLANATORY NOTE: For applications which meet the requirements of § 123.407(a), the health systems agency shall use procedures and apply criteria (to the extent applicable to enable it to make a recommendation on need) as required by this subpart. Health systems agencies may wish to expedite the reviews of applications intended to correct deficiencies which pose a threat to the public health. In so doing, health systems agencies may use any exceptions to the required review procedures which have been approved under § 122.309. See also the explanatory note which follows § 123.407.

§ 122.307 Adoption and public notice of review procedures and criteria.

(a) Each health systems agency shall adopt, and review and revise as necessary, review procedures and criteria in accordance with the requirements of this subpart prior to conducting reviews.

(b) Before adopting the review procedures and criteria required by this subpart or any revisions of the procedures and criteria, the health systems agency shall give interested persons an opportunity to offer written comments on the procedures and criteria, or any revisions thereof, which it proposes to adopt.

(1) The health systems agency shall distribute copies of its proposed review procedures and criteria, and proposed revisions to them, to the agencies and other entities with which the health systems agency must coordinate its activities under section 1513(d) of the Act and its Designation Agreement; to units of general purpose local government within its health service area; to the State Agency and Statewide Health Coordinating Council of each State in which all or any part of the agency's health service area is located; to health systems agencies in contiguous health service areas; and to any agency which establishes rates for health care facilities or HMOs in its health service area.

(2) The health system agency shall publish, in one or more newspapers of general circulation in its health service area, a notice stating that review procedures and criteria, or revisions to them, have been proposed for adoption and are available at specified addresses for inspection and copying.

(3) A health system agency may request from the Secretary an exception to the requirement of paragraph (b)(2) of this section. The request must be in writing and must contain a detailed explanation of the reasons for the request and of the substitute publication procedures that the agency intends to follow if the exception is approved. The Secretary may grant an exception if the Secretary determines that the proposed substitute procedures do not adversely and substantially affect the rights of affected persons.

(c) Each health systems agency shall distribute copies of its adopted review procedures and criteria, and any revisions to them, to the agencies and other entities specified in paragraph (b)(1) of this section, to the Secretary, and to other persons upon request.

§ 122.308 Procedures for health systems agency review.

(a) The procedures adopted and used by a health systems agency for conducting the reviews covered by this subpart must include at least the following:

(1) *Review schedule.* Review of applications in accordance with a schedule established by the State Agency under § 123.410(a)(1) of this title, including the consideration together of applications that have been batched (see § 123.410(a)(1)) under the State Agency schedule.

(2) *Notification of the beginning of a review.* Timely written notification to affected persons and to the State Agency of the beginning of a review, and, if a person has asked the health systems agency to place the person's name on a mailing list maintained by the health systems agency, notification to the person. Notification must include the proposed schedule for the review, the period within which a public hearing held by the health systems agency under paragraph (a)(8) of this section may be requested by affected persons (as defined in § 123.401 of this title), and the manner in which notification will be provided of the time and place of any hearing so requested.

(i) For purposes of this paragraph, the date of notification is the date on which the notice is sent or the date on which the notice appears in a newspaper of general circulation, whichever is later.

(ii) Written notification to members of the public and third party payers may be provided through newspapers of general circulation in the health service area and public information channels; notification to all other affected persons must be by mail (which may be as part of a newsletter).

(3) *Review period.* Schedules which provide that no review shall take longer than the period specified by the appropriate State Agency under § 123.410(a)(3) of this title. If, after a review has begun, the health systems agency requires the applicant to submit additional information, it shall give the applicant at least fifteen days to submit the information. The health systems agency shall notify the applicant that the applicant may request that the State Agency extend the review period at least fifteen days.

(4) *Information requirements.* Provision for persons subject to a review to submit to the health systems agency, in the form and manner and containing the information which the health systems agency shall prescribe and publish, and information that the health systems agency may require concerning the subject of the review.

(i) The information requirements may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed.

(ii) The health systems agency may require no information of a person subject to review which is not prescribed and published as being required.

(iii) The health systems agency shall develop procedures to ensure that requests for information in connection with a review under this subpart are limited to only that information which is necessary for the health systems agency to perform the review.

(5) *Periodic reports.* Submission of periodic reports by providers of health services and other persons subject to review respecting the development of proposals subject to review.

(6) *Written findings.* Provision for written findings (including, as applicable, the required findings under § 122.305(b)) which state the basis for any recommendation made by the health systems agency. The health systems agency shall send written findings to the applicant and to the State Agency for the State in which the project is proposed, and to others upon request. In the case of a projet proposed by an HMO, the health systems agency shall also send these written findings to the appropriate regional office of the Department of Health and Human Services at the time they are sent to the applicant.

(7) *Notification of the status of a review.* Timely notification, upon request, of providers of health services and other persons subject to review under this subpart of the status of the health systems agency review, findings made in the course of the review, and other appropriate information respecting the review.

(8) *Public hearing in the course of review.* Provision for a public hearing in the course of review (and before the health systems agency makes its recommendation to the State Agency) if requested by an affected person.

(i) Health systems agencies shall provide at least 15 days from the date of written notification of the beginning of a review (see paragraph (a)(2) of this section) within which a public hearing during the course of the review may be requested by affected persons.

(ii) The health systems agency may not impose fees for the hearing.

(iii) When a hearing is requested, the health systems agency shall, prior to the hearing, provide notice of the hearing, in accordance with its procedure adopted under paragraph (a)(2) of this section.

(iv) The health systems agency shall provide an opportunity for any person to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing.

(v) In cases where a State Agency has delegated to the health systems agency the authority to hold hearings under § 123.410(a)(8) of this title, the health systems agency shall follow the procedures of that paragraph.

(9) *Annual reports of the health systems agency.* Preparation and publication, at least annually, of reports by the health systems agency of the reviews being conducted (including a statement concerning the status of each review) and of the reviews completed by the agency since the publication of the last report and a general statement of the findings and recommendations made in the course of those reviews.

(10) *Public access.* Access by the general public to all applications reviewed by the health systems agency and to all other written materials essential to any health systems agency review.

(11) *Conflicts of interest.* In the exercise of any reviews under this subpart, no member of a governing body, executive committee, or any entity appointed by a governing body or executive committee may vote on any matter respecting an applicant with which the member has (or within the twelve months preceding the vote, had) any substantial ownership, employment, medical staff, fiduciary, contractual, creditor, or consultative relationship. A governing body, executive committee, and any entity appointed by a governing body or executive committee shall require each of its members who has or has had such a relationship to make a written disclosure of the relationship before any action is taken by the body, committee, or entity with respect to the applicant and to make the relationship public at any meeting in which action is to be taken with respect to the applicant.

(12) *Coordination within an SMSA.* Each health systems agency whose health service area includes part of a standard metropolitan statistical area (as determined by the Office of Management and Budget) shall coordinate its certificate of need review activities with all other health systems agencies whose health service areas include part of the standard metropolitan statistical area. This coordination shall include at least an opportunity to offer written comments on the procedures and criteria, or any revisions thereof, which it proposes to adopt in accordance with § 122.307.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed.

(c) The procedures may provide that the requirements of paragraph (a)(2) of this section shall be considered satisfied if the appropriate State Agency, in providing notice of the beginning of the review under § 123.410(a)(2) of this title, provides the information described in paragraph (a)(2) of this section.

(d) The procedures may provide that the requirements of paragraph (a) (4) or (5) of this section shall be considered satisfied if the appropriate State Agency has provided for the corresponding procedure found at § 123.410(a) (4) or (5) of this title.

§ 122.309 Exceptions to use of procedures.

(a) The Secretary may approve an exception to any of the required review procedures under § 122.308 either in response to a written request from the health systems agency or as a general exception of which any health systems agency may avail itself. In approving a general exception the Secretary will establish substitute procedures where appropriate. Before availing itself of a general exception approved by the Secretary, the health systems agency shall follow the notice and comment procedures of § 122.307(b).

(b) Before submitting a written request for an exception under this section, the health systems agency shall follow the notice and comment procedures of § 122.307(b) and shall submit to the Secretary with its request copies of all comments which it receives. Before approving the request, the Secretary will (1) review copies of the comments submitted by the health systems agency and, (2) determine that the procedures to be used are consistent with the purposes of the Act and will not adversely and substantially affect the rights of affected persons.

(c) The health systems agency shall, in accordance with the requirements of § 122.307(c), distribute a notice of the approved exceptions and of any substitute procedures established under this section.

§ 122.310 Criteria for health systems agency review.

(a) The health systems agency shall adopt, and use as applicable, specific criteria for conducting the reviews covered by this subpart. The criteria must be based at least on the general considerations listed under § 123.412(a) of this title, except that in the case of an HMO or an ambulatory care facility or health care facility controlled, directly or indirectly, by an HMO or combination of HMOs, the criteria must be based only on the considerations set forth in § 123.412(a)(13) of this title. The health systems agency may not adopt any additional criteria which are inconsistent with those criteria based on the general considerations listed under § 123.412(a).

(b) Health systems agencies shall apply all applicable criteria based on the considerations listed at § 123.412. Criteria adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.

§ 122.311 Required findings on access.

(a) For each project described in § 123.413(a) of this title for which the health systems agency recommends issuance of a certificate of need, the health systems agency shall make a written finding (which must take into account the current accessibility of the facility as a whole) on the extent to which the project will meet the health systems agency's criteria based on the considerations in § 123.412(a) (5) and (6).

Subpart E—Health Systems Agency Reviews of Certain Proposed Uses of Federal Health Funds

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); sec. 1513(e) of the Public Health Service Act, 88 Stat. 2238 (42 U.S.C. 300 *l*-2(e)).

SOURCE: 44 FR 47084, Aug. 10, 1979, unless otherwise noted.

§ 122.401 Purpose and applicability.

(a) Section 1513(e) of the Public Health Service Act provides that each health systems agency shall review and approve or disapprove certain proposed uses of Federal funds within the health service area for which the health systems agency is designated. In addition, section 1513(e) provides that a health systems agency may only review and comment on certain proposed uses of Federal funds by Indian tribes or inter-tribal organizations. The primary purpose of these reviews is to ensure that, to the extent feasible, these proposed uses of funds which are subject to review under section 1513(e) are consistent with and will help to implement the plans of the health systems agencies.

(b) The regulations of this subpart are applicable to the performance by a health systems agency of any review under section 1513(e) of the Act and in accordance with the designation agreement.

NOTE: Under 42 CFR 122.106(c), a health systems agency may not review and approve proposed uses of Federal funds within its health service area during its first year of conditional designation. It may not in any event perform this function until it has established a health systems plan and annual implementation plan in accordance with section 1513(b) (2) and (3) of the Act and has received written authorization from the Secretary.

§ 122.402 Definitions.

In addition to the terms defined in Subpart A of this part, as used in this subpart:

"Applicant" means a person applying to a Federal funding agency for a grant, loan or loan guarantee, or submitting to a Federal funding agency a proposal for a contract, reviewable under this subpart; or, in the case of funds made available by a State from an allotment to the State, a person applying to a State program agency for a grant or contract reviewable under this subpart.

"Construction" includes:

(1) The construction of new buildings and the acquisition, expansion, remodeling, replacement, and alteration of existing buildings; and

(2) Equipping new buildings and existing buildings, whether or not expanded, remodeled, or altered.

"Development of health resources" means activities which directly result in the generation of new health resources or the improvement, including consolidation of existing health resources. It includes, but is not limited to, education and training of health professions personnel, the development of facilities or services, and arrangements to provide services.

"Expansion of health resources" means any activity which will result in a substantial and significant increase in the quantity of health resources.

"Federal funding agency" means the organizational component of the Department of Health and Human Services which has the authority to make a grant, contract, loan, or loan guarantee reviewable under this subpart.

"Health resources" includes health services, health professions personnel, and health care facilities. For purposes of this subpart:

(1) "Health services" means screening, prevention, diagnostic, treatment, habilitative or rehabilitative services; it includes alcohol, drug abuse, mental health, preventive and environmental health services, and health information, education and promotion,

(2) "Health professions personnel" means individuals whose main occupation is the delivery of health services, and

(3) "Health care facilities" has the meaning given it in § 122.301(b) of this part.

"Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies, and insurance companies), a State, or political subdivision or instrumentality (including a municipal corporation) of a State.

"State program agency" means the agency of State government submitting a State plan or application to the Secretary as a condition to the receipt by any person of any funds under allotments made to States reviewable under this subpart.

"Support of health resources" means the furnishing of resources needed to provide a health resource, including money, manpower, equipment, facilities, supplies or consultative service.

[44 FR 47084, Aug. 10, 1979; 44 FR 49454, Aug. 23, 1979]

§ 122.403 General.

(a) Except as provided in paragraph (b), (c) and (d) of this section, each health systems agency shall, in accordance with applicable provisions of this subpart, review and approve or disapprove each proposed use within its health service area of Federal funds—

(1) Appropriated under the Public Health Service Act, the Community Mental Health Centers Act, sections 409 and 410 of the Drug Abuse Office and Treatment Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 for grants, contracts, loans or loan guarantees for the development, expansion, or support of health resources; or

(2) Made available by the State in which the health service area is in whole or in part located (from an allotment to the State under an Act referred to in paragraph (a)(1) of this section) for grants or contracts for the development, expansion, or support of health resources.

NOTE: Grants, loans and loan guarantees made directly by the Secretary to applicants within States from allotments to States are subject to review under paragraph (a)(1) of this section.

(b) A health systems agency shall review and comment on, but shall not approve or disapprove, each proposed use within its health service area of Federal funds described in subparagraph (a) of this section by an Indian tribe or inter-tribal Indian organization for any program or project which will be located within or will specifically serve—

(1) A Federally-recognized Indian reservation,

(2) Any land area in Oklahoma which is held in trust by the United States for Indians or which is a restricted Indian-owned land area, or

(3) A Native village in Alaska (as defined in section 3(c) of the Alaska Native Claims Settlement Act).

(c) A health systems agency shall not review and approve or disapprove proposed uses of Federal funds which are (i) non-competing extension grant applications, or (ii) supplemental grant applications which are for administrative increases in costs.

§ 122.404 Section 1536 States.

(a) For any proposed use of Federal funds in the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, American Samoa, the Northern Marianas Islands, or any other State determined by the Secretary to meet the requirements of section 1536(a) of the Act, the requirements of this subpart shall, except where otherwise stated, apply to the State health planning and development agency if that Agency has received a grant from the Secretary under section 1516 of the Act. Under these circumstances the State will be treated as a health service area and the State Agency a health systems agency for the area.

(b) A State Agency in a State covered by paragraph (a) of this section may not review and approve proposed uses of Federal funds within its State during its first year of conditional designation, and may not in any event perform this function until

(1) The Statewide Health Coordinating Council (SHCC) has established a State health plan for the State in accordance with section 1524(c) of the Act and 42 CFR 123.110(a), and

(2) The Secretary has in writing authorized the State Agency to perform this function.

(c) A State Agency in a State covered by paragraph (a) of this section shall afford the SHCC for the State a reasonable opportunity to review and comment upon each proposed use which it will review before approving or disapproving it.

§ 122.405 Involvement of more than one health systems agency.

Where a proposed use of Federal funds would involve the development, expansion or support of health resources in more than one health service area, references in this subpart to "the health systems agency" refer to the health systems agency for each health service area. The health systems agency in the health service area from which the applicant will administer the project (a) shall coordinate the reviews by all of the health systems agencies involved, except that it may delegate coordinating responsibility to a health systems agency in whose health service area a major portion of the funds will be used, and (b) may be delegated the review authority by the other health systems agencies involved. If some of the health systems agencies involved approve the proposed use and some disapprove, the decision of each health systems agency will apply to the use of funds in its own health service area.

§ 122.406 Determination of proposed uses subject to review by health systems agencies.

(a) The Secretary will publish as uncodified appendices to this subpart, and will revise from time to time, lists of Federal programs which include proposed uses covered by paragraph (a) of § 122.403. These appendices will be for informational purposes only. The fact that a program is not listed does not mean, if paragraph (a) of § 122.403 is otherwise applicable, that the proposed use is not subject to review.

(b) In certain programs which are listed under paragraph (a) of this section, there may be individual proposed uses of Federal funds which are not for the development, expansion, or support of health resources, and therefore are not subject to review under § 122.403(a). Also, there may be proposed uses of Federal funds in unlisted programs which are subject to review under § 122.403 of this subpart. Accordingly, either an applicant or a health systems agency may, in accordance with procedures prescribed by the Secretary, request the Federal funding agency to determine whether any particular proposed use of Federal funds is subject to review and approval or disapproval by a health systems agency. The Federal funding agency will promptly notify both the applicant and the health systems agency of its determination. Where the Federal funding agency concludes on its own initiative that a particular proposed use of Federal funds in a program generally covered by § 122.403(a) is not subject to review and approval or disapproval by a health systems agency, it will promptly notify the applicant and the health systems agency of that determination.

§ 122.407 [Reserved]

§ 122.408 Procedures for submission of applications.

(a) *General.* Except as otherwise specified in this section applications for Federal funds must be submitted at the times and in the form and manner prescribed by the Secretary or, in the case of funds made available by a State under an allotment program covered by § 122.403(a)(2), by the State program agency.

(b) *HSA review of direct Federal grants, contracts, loans, and loan guarantees.* An application for a grant, loan, or loan guarantee or a proposal for a contract which is subject to review by a health systems agency under § 122.403(a)(1) must be submitted simultaneously to the health systems agency and the Federal funding agency. However, the Secretary may, for certain Federal funding programs or types of applications, require that they be submitted first to the health systems agency and then, following approval or disapproval by the health systems agency or the expiration of the period for health systems agency review, whichever comes first to the Federal funding agency, or (ii) directly to the Federal funding agency, which will, before approving the application or proposal and at a time it considers appropriate, submit it or a summary thereof, to the health systems agency: *Provided, that:*

An application for a noncompeting continuation grant shall be submitted to a health systems agency for review and approval or disapproval in accordance with paragraph (b)(1) of this section upon the request of the health systems agency, or when the applicant proposes a change in the funding level of 20 percent or more from that previously approved by the Federal funding agency, or when the applicant or the Federal funding agency determines that there has been a substantial change in the proposed or actual use of funds, or, if no other submission is made under this paragraph, every five years, beginning with the effective date of these regulations.

(1) A request by a health systems agency for submission to it of an application for a noncompeting continuation grant will be effective only if it is received by the Federal funding agency at least nine months before the scheduled date of the continuation grant award.

(2) A copy of each application for a noncompeting continuation grant not subject to review under this subparagraph shall be provided by the applicant to the health systems agency at the time the application is submitted to the Federal funding agency or, if the application is also submitted to the clearinghouse established pursuant to Office of Management and Budget Circular A-95 at the earlier of the two times.

(3) If an application contains material which the applicant believes to be confidential or proprietary and therefore believes should not become public, the applicant may submit a summary of this material to the Federal funding agency. Upon determination by the Federal funding agency that (i) the material is confidential or proprietary, and (ii) the summary is full and accurate, the applicant may submit the summary to the health systems agency along with the applica-

tion, deleting the portion of the application which has been summarized.

(c) *Proposed uses of allotment funds.* A proposal for using funds available from a State allotment which is subject to HSA review under § 122.403(a)(2) must be submitted to the HSA by the State program agency, or at the option of the State program agency, by the applicant according to procedures established by the State program agency.

(1) The State program agency must provide an opportunity for the SHCC and the HSAs in the State to comment on its proposed procedures prior to their adoption.

(2) The procedures must provide for a minimum of 60 days for the HSA and SHCC to review the proposed uses of allotment funds subject to review under § 122.403(a).

[44 FR 47084, Aug. 10, 1979; 44 FR 49455, Aug. 23, 1979]

§ 122.409 Adoption and public notice of health systems agency review procedures and criteria.

(a) Prior to performance of any review under section 1513(e) of the Act, and in accordance with its designation agreement, each health systems agency must, except as provided in § 122.411 of this subpart, adopt review procedures and criteria which meet the requirements of §122.410 and § 122.412, respectively, of this subpart.

(b) Before adopting the review procedures and criteria required by this subpart or any revisions to them, the health systems agency must give interested persons an opportunity to offer written comments on them, or on the revisions, which it proposes to adopt as follows:

(1) The health systems agency must distribute copies of its proposed review procedures and criteria and proposed revisions, to the agencies, institutions and associations with which the agency must coordinate its activities under section 1513(d) of the Act and its designation agreement, to units of general local government within its health service area, or to regional multi-purpose planning bodies which represent such units with respect to health matters, to the State Agency and Statewide Health Coordinating Council of each State in which all or any part of the agency's health service area is located, and to health systems agencies designated for health service areas contiguous to its own.

(2) The health systems agency must publish, in one or more newspapers of general circulation in its health service area, a notice stating that reivew procedures and criteria, or revisions to them, have been proposed for adoption and are available at specified addresses for inspection and copying. A health systems agency may request from the Secretary an exception to this requirement. This request must be in writing, shall contain a detailed explanation of the reasons for the request and of the substitute publication procedures that the agency intends to follow if the exception is approved. The Secretary may grant an exception if he determines that the proposed substitute procedures are less costly or more effective and do not adversely and substantially affect the rights of persons affected by the reviews.

(3) The health systems agency must allow 30 days from the date of publication of the notice for persons to submit written comments on the proposed review procedures and criteria, or any revision to them, prior to their adoption.

(c) Each health systems agency must distribute copies of its adopted review procedures and criteria, and any revisions, to the agencies and organizations specified in paragraph (b)(1) of this section, and to the Secretary, and must provide copies to other persons upon request. The health systems agency may not impose fees for distribution to the agencies and organizations specified in paragraph (b)(1) or to the Secretary.

[44 FR 47084, Aug. 10, 1979; 44 FR 49455, Aug. 23, 1979]

§ 122.410 Procedures for health systems agency review.

(a) The procedures adopted and used by a health systems agency for conducting reviews under section 1513(e) of the Act and this subpart shall include at least the following:

(1) Written notification to affected persons of the beginning of a review.

The health systems agency must send this notification within seven (7) days of receipt of the application. It must include both a review schedule and a dealine for requesting a public hearing by persons directly affected by the review as defined in paragraph (a)(7) of this section. The manner of providing notification concerning time and place of any requested hearing must also be included. Requests for a hearing must be made within a reasonable period of time from the transmittal of the written notification. For purposes of this subparagraph, "affected persons" include, at a minimum:

(i) The person (hereinafter referred to as the "applicant") whose application for a proposed use of Federal funds (hereinafter referred to as the "project") is being reviewed;

(ii) All other health systems agencies serving health service areas whose residents are proposed to be served by the project;

(iii) The State Agency and the State program agency for each State in which the project is proposed to be conducted;

(iv) Entities located in the health systems agency's health service area which provide services or conduct activities similar to the proposed services or activities under review or which, prior to the receipt by the health systems agency of the application for review, have formally indicated an intention to provide similar services or conduct similar activities in the future;

(v) Entities with which the health systems agency must coordinate its activities under section 1513(d) of the Act, including the clearinghouses established under Office of Management and Budget Circular A-95;

(vi) Any agency which establishes rates for health care facilities or health maintenance organizations (HMOs) in its health service area, and;

(vii) Those members of the public who are to be served by the proposed project. Written notification to members of the public who are to be served by the proposed project. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channel notification to all other affected persons shall be by mail (which may be as part of a newsletter). The health systems agency must simultaneously provide written notification to the Federal funding agency.

(2) Schedules for reviews which provide that not longer than 60 days will elapse from the date of notification made in accordance with paragraph (a)(1) of this section to the date of the written findings made in accordance with paragraph (a)(5) of this section, unless the Federal funding agency has specified a longer period with respect to a particular program or particular proposed use of Federal funds covered by this subpart.

(3) Provisions for applicants to submit information at the request of the health systems agency concerning the project. This information must be submitted in the form and manner that it prescribes and publishes.

(4) Submission of periodic reports by providers of health services and other persons subject to health systems agency review under this subpart respecting the development of proposals subject to review.

(5) Provision for written findings which state the basis for any final decision or recommendation made by the health systems agency. Those findings must be sent to the applicant, to the State Agency and State program agency for each State in which the project will be conducted, and to the Federal funding agency, and must be available to others upon request.

(6) Notification, upon request, to applicants and other persons subject to health systems agency review under this subpart of the status of the agency review of projects, of findings made in the course of this review, and other appropriate information respecting the review.

(7) Provision for public hearing in the course of agency review if requested by one or more persons directly affected by the review. The agency may not impose fees for a hearing. For purposes of this subparagraph, "persons directly affected" by the review include, at a minimum, the applicant, entities with which the health systems agency must coordinate its activities under section 1513(d) of the Act, enti-

ties located in the health systems agency's health service area which provide services or conduct activities similar to the proposed services or activities under review or which, prior to the receipt by the health systems agency of the application for review, have formally indicated an intention to provide similar services or conduct similar activities in the future, and members of the public who are to be served by the proposed project. Where a hearing is requested, the agency must, prior to the hearing, provide notice of it, in accordance with its procedure adopted under paragraph (a)(1) of this section. The procedure for a hearing must provide an opportunity for any person to present testimony.

(8) Preparation and publication, at least annually, of reports by the health systems agency of the reviews being conducted (including a statement concerning the status of each such review) and of the reviews completed by the agency since the publication of the last report and a general statement of the findings and decisions made in the course of these reviews.

(9) Access by the general public to all applications received by the health systems agency and to all other written materials pertinent to any agency review.

(10) Persons proposing construction projects must submit a letter of intent to the health systems agency at the earliest opportunity. The letter of intent must contain sufficient detail to adequately inform the agency about the scope and nature of the project.

(11) Provision during its review for coordination and consultation with other health systems agencies reviewing the same project.

(12) Provision for agency coordination, to the maximum extent possible, of its reviews of projects under this subpart and its reviews of proposed new institutional health services under Subpart D of this part.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed.

§ 122.411 Exceptions to use of health systems agency procedures.

After following the procedure set forth in § 122.409(b) of this subpart an agency may, with respect to any type of group of reviews, request from the Secretary an exception to the requirement of § 122.409(a) that it utilize review procedures which meet the requirements of § 122.410. This request must be in writing, must contain a detailed explanation of the reasons for the request and of the substitute review procedures that the agency intends to follow if the exception is approved, and must be accompanied by copies of all written comments submitted under § 122.409(b) to the agency with respect to the request of an exception. The Secretary may grant such an exception if he determines that the proposed substitute procedures are less costly or more effective, are consistent with the purposes of the Act, and do not adversely and substantially affect the rights of persons affected by the subject reviews. The health systems agency must distribute copies of substitute procedures approved by the Secretary in accordance with the requirements of § 122.409(c) of this subpart.

§ 122.412 Criteria for health systems agency review.

(a) The health systems agency shall adopt and utilize as appropriate specific criteria for conducting the reviews covered by this subpart. The criteria must include at least the following general considerations:

(1) The relationship of the health services being reviewed to the applicable health systems plan and annual implementation plan adopted under section 1513(b) (2) and (3), respectively, of the Act.

(2) The relationship of services reviewed to the long-range development plan (if any) of the person providing or proposing the services.

(3)(i) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups are likely to have access to those services.

(ii) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups to obtain needed health care.

(4) The availability of alternative, less costly, or more effective methods of providing the services.

(5) The immediate and long-term financial feasibility of the proposal and the probable impact of the proposal on the costs of and charges for providing health services in the health service area.

(6) The relationship of the services proposed to be provided to the existing health care system of the area in which such services are proposed to be provided.

(7) The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of the services proposed to be provided and the availability of alternative uses of resources for the provision of other health services.

(8) The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services in the health service areas in which the proposed health services will be provided.

(9) The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.

(10) The special needs and circumstances of health maintenance organizations (HMOs) for which assistance may be provided under Title XIII of the Act. These needs and circumstances must be limited to:

(i) The needs of enrolled members and reasonably anticipated new members of the HMO or proposed HMO for the health services proposed to be provided by the organization.

(ii) The availability of these health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO or proposed HMO. In assessing the availability of such health services from non-HMO providers or other HMOs, the agency must consider only whether the health services from these providers:

(A) Would be available under a contract of at least five years duration;

(B) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO or proposed HMO. (For example—whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);

(C) Would cost no more than if the health service were provided by the HMO or proposed HMO; and

(D) Would be available in a manner which is administratively feasible to the HMO or proposed HMO.

(iii) Other factors the agency may propose and the Secretary may, in accordance with paragraph (c) of this section, find to be consistent with the purpose of Title XIII of the Act.

(11) The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

(12) The contribution of the project in meeting the health related needs of members of medically underserved groups and members of groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low income persons, racial and ethnic minorities, women, and handicapped persons), particularly those needs identified in the applicable health systems plan and annual implementation plan as deserving of priority.

(13) In the case of a construction project:

(i) The costs and methods of the proposed construction, including the costs and methods of energy provision;

(ii) The probable impact of the construction project reviewed on the costs of providing health services by the person proposing the construction project; and

(iii) The relationship of the construction project to the State medical facilities plan approved under section 1603 of the Act.

(14) The special circumstances of health care institutions with respect to the need for conserving energy.

(b) Criteria adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.

(c) Where an agency proposes under paragraph (a)(10)(iii) of this section that it be permitted to base its reviews of health maintenance organizations on criteria which consider factors not set forth in paragraph (a)(10) of this section, it must do so in a written request to the Secretary, specifying the reasons for the proposal. The Secretary will approve the request if he finds the additional factors to be consistent with the purpose of Title XIII of the Act. Unless the Secretary has approved the additional factors, the agency shall base its review solely on the factors set forth in paragraph (a)(10) of this section.

[44 FR 47084, Aug. 10, 1979; 44 FR 49455, Aug. 23, 1979]

§ 122.413 Period for health systems agency review.

Notwithstanding any provision of any Act referred to in § 122.403, a health systems agency must be allowed not less than 60 days to make the review required by that section.

(a) Unless the appropriate Federal funding agency or (if allotment funds are involved), State program agency specifies in writing a longer period with respect to a program or particular proposed use of Federal funds covered by this subpart, the period for health systems agency review of any proposed use must be 60 days, except that the health systems agency may, at its option, complete its review in a shorter period.

(b) The period for health systems agency review shall begin on the date that notification of the beginning of the review is sent to affected persons in accordance with § 122.410(a)(1).

(c) Where a proposed use of Federal funds is submitted to a health systems agency for its review less than 120 days prior to the end of the period of availability of the funds involved, the Federal funding agency may, at its option, after consultation with the appropriate health systems agency and following its determination that the application could not reasonably have been submitted to the health systems agency at least 120 days prior to the end of the period of availability of funds, make the grant, loan or loan guarantee or award the contract so as to preserve the availability of the funds. Any such grant, loan, loan guarantee or contract must, however, be subject to the condition that no Federal funds may be expended until

(1) The health systems agency has approved the proposed use of Federal funds, or

(2) The health systems agency has notified the Federal funding agency that it will not disapprove the proposed use of Federal funds, or

(3) The period for HSA review has passed without the HSA having notified the Federal funding agency of its disapproval, or

(4) The Secretary has determined, notwithstanding the health systems agency's disapproval to make such funds available in accordance with § 122.415(d).

[44 FR 47084, Aug. 10, 1979; 44 FR 49455, Aug. 23, 1979]

§ 122.414 Notification of health systems agency approval or disapproval.

Not later than the close of the first business day following the end of the period described in § 122.413 for review of a proposed use of Federal funds, the health systems agency shall provide written notification to the applicant, the appropriate Federal funding agency, the State Agency, and the State program agency for each State in which the project is proposed to be conducted of its approval or disapproval of the proposed use, setting forth the reasons for such approval or disapproval.

(a) Mailing of the required notification shall be deemed a provision of notification for purposes of this section and § 122.410(a)(6).

(b) Following the end of the review period described in § 122.413, any proposed use of Federal funds with respect to which notification has not been provided by the health systems agency in accordance with this section shall be deemed not to have been disapproved by the health systems agency.

§ 122.415 Consequences of health systems agency disapproval.

(a) *General.* If a health systems agency, in accordance with applicable provisions of this subpart, disapproves a proposed use in its health service area of Federal funds, the Secretary may not make such Federal funds available for such use until he has made, upon the request of the entity making such proposal, a review of the agency decision.

(b) *Procedures for requesting review.* To be effective, a request for review must be:

(1) Provided (including mailing) to the Federal funding agency, in such form and manner as may be prescribed by the Federal funding agency, not later than 15 days after the provision of notice to the applicant of disapproval of the proposed use of Federal funds by the health systems agency in accordance with § 122.414; and

(2) Accompanied by a justification for approval by the Secretary of the proposed use of Federal funds despite the health systems agency's disapproval, including detailed responses to the reasons given by the health systems agency for its disapproval.

(c) *State Agency comments.* In making his review of a health systems agency disapproval under this section, the Secretary will give the appropriate State Agency and health systems agency 15 days in which to consider the disapproval and to provide its comments on the disapproval to the Secretary.

(1) To assist the State Agency in considering a health systems agency disapproval under this paragraph, the Secretary will provide the State Agency with copies of the request for review and any material accompanying the request furnished under paragraph (b) of this section. The Secretary will at the same time provide a copy to the health systems agency and request its comments.

(2) To be considered under this paragraph, comments by a State Agency or health systems agency must be mailed or otherwise provided to the Secretary not later than 15 days after the information described in paragraph (c)(1) of this section is mailed or otherwise provided to the State Agency.

(d) *Review by the Secretary.* The Secretary, after taking into consideration comments received from the State Agency in accordance with paragraph (c) of this section, may make the Federal funds available for use, notwithstanding the disapproval of the health systems agency. Each decision by the Secretary to make funds available despite the disapproval of a health systems agency will be submitted to the applicant and the appropriate health systems agency and State Agency, and will contain a detailed statement of the reasons for the decision. In reviewing a health systems agency's disapproval under this paragraph, the Secretary will consider at least the following:

(1) Whether the health systems agency substantially adhered to the applicable review procedures adopted by the health systems agency under this subpart.

(2) Whether the proposed use of Federal funds is consistent with the applicable review criteria adopted by the health systems agency under this subpart.

(3) Whether the failure to make the proposed Federal funds available will adversely affect the health of residents of the health service area or of other health service areas.

(4) Whether the proposed use of Federal funds meets a national or regional need for which local conditions offer special advantages and which is unlikely to be accomplished efficiently

or effectively in another health service area.

Subpart F—Health Systems Agency Reviews of Existing Institutional Health Services for Appropriateness

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 1513 and 1532 of the Public Health Service Act, as amended, 93 Stat. 592-630 (42 U.S.C. 300l-2, 300n-1).

SOURCE: 44 FR 71769, Dec. 11, 1979, unless otherwise noted.

§ 122.501 Definitions.

Except for the term "institutional health services," terms used in this subpart shall have the meaning given them in Subparts A (Definitions) and D (Procedures and Criteria for Review of New Institutional Health Services) of this part. In addition, as used in this subpart:

The term "institutional health services" means health services which (a) are provided through private or public hospitals, rehabilitation facilities, and nursing homes, and (b) entail annual operating costs of at least the expenditure minimum. For purposes of this paragraph, the term "expenditure minimum" means $75,000 for the twelve month period beginning with October 1979, and for each twelve month period thereafter, $75,000 or, at the discretion of the State, the figure in effect for the preceding twelve month period, adjusted to reflect the change in the preceding twelve month period in an index to be specified by the Secretary.

The term "existing institutional health services" or "services" means institutional health services:

(a) Being offered in the health service area at the time of review for appropriateness, or

(b) Offered at any time in the 12 months prior to the review and also planned to be offered at any time in the 12 months following the review, or

(c) Which will be offered during the 12 months following the review.

A finding of "appropriateness" means a finding that a service meets the needs of a population, in accordance with the criteria development and published under § 122.507.

The term "areawide review" means the review of a specific institutional health service as delivered by all the institutions providing the service in the health service area (a) which shall culminate in recommendations regarding the appropriateness of that service over the entire health service area, and (b) which may result in recommendations regarding the appropriateness of that service in a particular institution.

§ 122.502 Purpose and applicability.

Section 1513(g) of the Act requires each health systems agency to review on a periodic basis, but at least every 5 years, all institutional health services offered in its health service area and to make recommendations to the State Agency for each State in which any part of the health systems agency's health service area is located respecting the appropriateness in the area of such services (hereinafter referred to as an appropriateness review). Section 1532(a) of the Act requires that in performing its review functions under section 1513(g) of the Act or in conducting any other reviews of existing health services, each health systems agency shall follow procedures and apply criteria developed and published by the health systems agency in accordance with regulations of the Secretary. This subpart sets forth minimum procedures and criteria to be used by health systems agencies in conducting these reviews and the requirements respecting the assumption, conduct, and timing of the appropriateness review function by health systems agencies; requirements respecting the coordination with the State Agency and the Statewide Health Coordinating Council; and the administrative steps which are necessary for the effective performance of the appropriateness reviews.

NOTE: Under 42 CFR 122.106(c), a health systems agency may not perform the appropriateness review function during its first year of conditional designation, and may not in any event perform this function during its period of conditional designation until it has established a health systems plan and annual implementation plan in accordance with sections 1513(b)(2) and (3) of the Act, and the Secretary has in writing authorized the agency to perform this function.

§ 122.503 Appropriateness review work program.

(a) Each appropriateness review shall be performed on an areawide basis and shall result in a finding as to the appropriateness of the service being reviewed as it is delivered in the health service area. The health systems agency may, at the same time, make findings as to the appropriateness of that service in particular institutions.

(b) The work program submitted by each health systems agency in accordance with 42 CFR 122.104(a)(3) or (b)(9), whichever is applicable, shall with respect to the assumption and continuing performance of the appropriateness review function:

(1) Specify the steps to be taken to develop procedures and criteria to be applied in performance of appropriateness reviews, in consultation with the Statewide Health Coordinating Council and State Agency of each State in which any part of the health systems agency's health service area is located;

(2) Include an assurance (i) that the health systems agency will abide by the decision of the State Agency with respect to the definitions of services, priorities among services, and the schedule for areawide reviews of such services if the State Agency written decision is communicated to the health systems agency within 6 months following publication of these regulations; or after such time (ii) that the health systems agency will abide by the definitions of services and schedules for reviews agreed to by the majority of the health systems agencies in the State, and will give priority in its reviews to services for which National Guidelines for Health Planning have been issued.

(3) Provide for the establishment of administrative procedures governing the transmittal of appropriateness review recommendations to the State Agency in accordance with procedural requirements established by the State Agency; and

(4) Specify the steps necessary to complete areawide appropriateness reviews of all existing institutional health services within 3 years of the date of the health systems agency's initial full designation and during each succeeding 5-year period. Review schedule priorities may be established, but such review priority setting shall not result in the exclusion from review of any existing institutional health service during any applicable time period.

(c) Each health systems agency shall, within three months after the effective date of these regulations, submit to the Secretary a revised work program under § 122.104(a)(3) or (b)(9) of this title, whichever is applicable, which conforms to the requirements of this section.

§ 122.504 Adoption and public notice of review procedures and criteria.

The provisions of 42 CFR 122.305 apply to the adoption and public notice of review procedures and criteria under this subpart.

§ 122.505 Procedures for health systems agency review.

(a) The procedures adopted and used by a health systems agency conducting the reviews covered by this subpart shall include at least the following:

(1) Written notification to affected persons of the beginning of a review. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels; notification to all other affected persons shall be by mail (which may be as part of a newsletter). "Affected persons" include at a minimum, the person whose service is being reviewed, the State Agency for each State in which all or any part of the agency's health service area is located, health systems agencies serving contiguous health service areas, health care facilities and HMOs located in the health service area which provide institutional health services, entities with which the health systems agency must coordinate its activities pursuant to section 1513(d) of the Act, any agency which establishes rates for health care facilities or HMOs in its health service area, and those members of the public

who are to be served by the service subject to review.

(2) Schedules for areawide reviews which provide that no review shall, to the extent praticable, take longer than 180 days from the date of notification to affected persons made in accordance with paragraph (a)(1) of this section to the date of submission of the health systems agency's recommendations to the State Agency.

(3) Provision for persons subject to a review to submit to the health systems agency such information as the health systems agency may require concerning the subject of such review, in the form and manner and containing the information which the health systems agency shall prescribe and publish. Such information requirements may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed; however, the health systems agency may require no information of a person subject to review which is not prescribed and published as being required in accordance with § 122.504.

(4) Provision for written findings which state the basis for any recommendations made by the health systems agency.

(5) Notification of providers of health services and other persons subject to the health systems agency review of the status of the health systems agency's review of the institutional health services, findings made in the course of the review, and other appropriate information respecting the review.

(6) Provision for (i) public hearings in the course of the health systems agency review if requested by persons affected by the review, and (ii) that any person may, for good cause shown, request in writing a public hearing for purposes of reconsideration of a health systems agency recommendation derived from an institution-specific finding.

(7) Preparation and publication of regular reports by the health systems agency of the reviews being conducted (including a statement concerning the status of each such review), and of the reviews completed by the health systems agency (including a general statement of the findings made in the course of these reviews and the recommendations made to the State Agency) since the publication of the last report.

(8) Access by the general public to all written materials pertinent to any health systems agency review.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed.

(c) The procedures adopted for reviews may provide that the requirements of paragraph (a)(3) of this section shall be deemed satisfied for any health service area within the State if the State Agency has provided for a corresponding procedure.

§ 122.506 Exceptions to use of procedures.

A health systems agency may, with respect to any type or group of reviews, request from the Secretary an exception to the requirement that it use review procedures which meet the requirements of § 122.506. The requirements of 42 CFR 122.307 apply to such a request for an exception.

§ 122.507 Criteria for health systems agency review.

The provisions of 42 CFR 123.607 apply to the adoption and use of review criteria under this subpart.

§ 122.508 Required recommendations.

(a) After completing its review of an existing institutional health service a health systems agency shall make recommendations respecting the appropriateness of the service in its health service area to the State Agency of each State in which all or any part of the health systems agency's health service area is located.

(b) A health systems agency may not recommend that a State Agency find an existing institutional health service to be inappropriate unless the health systems agency has stated in writing that the service has not met one or more of the established criteria of the health systems agency and the ways in which the service failed to meet the criteria, including any that are beyond the control of the person(s) providing that service.

(c) A health systems agency, in conducting an areawide review which results in institution-specific findings may not recommend that an existing institutional health service provided by or through an HMO be found inappropriate solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same health service area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(d) When a health systems agency recommends to a State Agency that a service be found inappropriate, the health systems agency shall, to the extent practicable, suggest to the State Agency a plan for remedial action.

Subpart G—[Reserved]

Subpart H—Revision of Health Service Area Boundaries

Authority: Sec. 215 of the PHS Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 1511(b) of PHS Act, 88 Stat. 2229 (42 U.S.C. 300-1(b)(4)).

Source: 47 FR 30951, July 15, 1982, unless otherwise noted.

§ 122.701 Purpose.

Section 1511 of the Public Health Service Act requires the Secretary to establish health service areas throughout the United States. Section 1511(b)(4) directs the Secretary to review the appropriateness of these area boundaries upon his own initiative or at the request of a Governor or a health systems agency and under certain circumstances, to revise those boundaries. The purpose of these regulations is to set forth the procedures and criteria which apply to the revision of health service area boundaries under section 1511(b)(4) of the Public Health Service Act.

§ 122.702 General.

Any health service area boundary may be revised if, following the review of the appropriateness of that area boundary, the Secretary determines that (1) the boundary no longer meets the requirements of section 1511(a) of the Act, or (2) the proposed revised boundary would meet the requirements of that section in a significantly more appropriate manner in terms of the efficiency and effectiveness of health planning efforts. In making this determination, the Secretary will follow the procedures under § 122.706 and apply the criteria under § 122.705.

§ 122.703 Initiation of Review.

An area boundary may be revised by the Secretary upon the Secretary's own initiative or at the request of a Governor or health systems agency whose respective State or health service area is affected by the proposed revision.

§ 122.704 Request.

(a) Any Governor or agency requesting revision of a health service area boundary must consult with the following individuals and entities and must submit to the Secretary with the request written evidence of these consultations, together with any comments received from these individuals and entities:

(1) The Governor(s) of the State(s) and the Statewide Health Coordinating Council(s) (SHCC(s)) which would be affected by the revision;

(2) The chief executive officer or agency of each political subdivision within the State(s) or area which would be affected by the revision;

(3) The health systems agency(s) which would be affected by the revision.

(b) In addition, any request made under this paragraph must also include:

(1) A description of the proposed new area boundaries and a discussion of the reasons supporting the proposal;

(2) A description of the effect of the proposed revision on area population, the State and local health planning structure (particularly, the effect on agency governing body composition and funding), and on the relationship between the proposed revised area boundaries and areas for substate planning and development districts under OMB Circular A-95; and

(3) Evidence satisfactory to the Secretary that either of the requirements of § 122.702 is satisfied. This evidence

must at least include a description of the advantages and disadvantages of the proposed revision, with particular emphasis upon whether the proposed revision would in any way disrupt the State or local health planning activities.

§ 122.705 Criteria.

In determining whether either of the requirements of § 122.702 is satisfied, the Secretary will apply Sections D and E of the area redesignation guidelines (41 FR 39433, September 15, 1976), which are set forth in Appendix A of these regulations.

§ 122.706 Revisions.

Following the application of the criteria set forth in Appendix A, the Secretary will determine whether to revise an area boundary. Provided that—

(a) In the case of a review initiated by the Secretary, no boundary may be revised unless the Secretary has consulted with the individuals and entities listed in § 122.704(a);

(b) In the case of any proposed revision, the Secretary will publish a notice of the proposed revision and give any interested person an opportunity for a hearing.

(c) No revision which would comprise an entire State will be made without the prior consent of the Governor of that State.

§ 122.707 Notification.

Written notification of the Secretary's decision under § 122.706 will be provided to the Governor, the SHCC and the HSA affected by the revision. In addition, the Secretary will publish this decision in the FEDERAL REGISTER.

APPENDIX A—HEALTH SERVICE AREA REDESIGNATION—SECTIONS D AND E

(Published in the FEDERAL REGISTER on September 15, 1976 (41 FR 39433-4))

D. REDESIGNATION STATUTORY REQUIREMENTS

There are six substantive requirements enumerated in section 1511 of the Public Health Service Act that health service areas must meet.

1. With respect to population, section 1511(a)(3) of the Act requires:

"The area, upon its establishment, shall have a population of not less than five hundred thousand or more than three million; except that—

"(A) The population of an area may be more than three million if the area includes a standard metropolitan statistical area (as determined by the Office of Management and Budget) with a population of more than three million, and

"(B) The population of an area may—

"(i) Be less than five hundred thousand if the area comprises an entire State which has a population of less than five hundred thousand, or

"(ii) Be less than—

"(I) Five hundred thousand (but no less than two hundred thousand) in unusual circumstances (as determined by the Secretary),

"(II) Two hundred thousand in highly unusual circumstances (as determined by the Secretary),

"If the Governor of each State in which the area is located determines, with the approval of the Secretary, that the area meets the other requirements of this subsection."

This specific minimum-maximum population requirement was adopted from the House bill (H.R. 16204) by the Conferees. With respect to it, the House Committee Report (No. 93-1382, p. 52) stated that "The 500,000 people minimum reflects the experience that effective health planning can be conducted only with an adequate base of population and health resources to sustain a planning process."

While waivers of the minimum 500,000 population requirement may be allowed, the Committee noted in its Report that it did not intend that "waivers in either 'unusual' or 'highly unusual' circumstances be used frequently."

As regards waivers, it should be noted that a request to establish a single, Statewide health service area in a State with a population of less than 500,000 does not require a waiver, nor does the designation of a proposed area encompassing an SMSA with a population in excess of 3 million require one.

With respect to the latter, a designated health service area which includes an SMSA over 3 million may include territory in addition to the SMSA itself. On the other hand, while several SMSAs may be included in the same health service area, indeed frequently should be, the combined populations in the area may not exceed 3 million (unless one of the SMSAs has a population over 3 million).

The latest available annual population estimate from the Department of Commerce, which is available for all States and counties nationally, must be used in computing populations for purposes of area redesignation.

2. As regards SMSAs, section 1511(a) of the Act requires that—

"Each standard metropolitan statistical area shall be entirely within the boundaries of one health service area, except that if the Governor of each State in which a standard metropolitan statistical area is located determines, with the approval of the Secretary, that in order to meet the other requirements of this subsection a health service area should contain only part of the standard metropolitan statistical area than such statistical area shall not be required to be entirely within the boundaries of such health service area."

The House Committee Report (p. 53) states that "While health service areas should generally be larger than standard metropolitan statistical areas, the Committee has recognized SMSAs as useful delineations of our major metropolitan areas and feels very strongly that health service areas should not divide the SMSAs. Since SMSAs often cross State boundaries because metropolitan areas often do, the Committee intends that when a major metropolitan area straddles a State boundary its service area will also cross the State boundary. While provision is made for waiving this requirement with the approval of the Secretary, it is anticipated that the waiver will be granted rarely * * *." As regards this requirement, unless the Governor of each of the two or more States in which an SMSA is located requests that it be waived, the Secretary will not entertain the waiver request to split the SMSA.

3. Insofar as the geography of the area is concerned, section 1511(a)(1) requires that—

"The area shall be a geographic region appropriate for the effective planning and development of health services, determined on the basis of factors including population and the availability of resources to provide all necessary health services for residents of the area."

A number of factors or considerations are relevant to this general requirement. They include but are not necessarily limited to the following:

a. Time, distance, and cost factors in relation to health care services and facilities within a region that in effect constitute significant economic and/or geographic barriers to obtaining care.

b. Functional economic areas (as defined by the Bureau of Economic Analysis, U.S. Department of Commerce).

c. State boundaries (except in the case of inter-State SMSAs) and those of local political subdivisions. Many funding and other decisions of State and local general-purpose governments are highly relevant to health planning, resource development, and regulatory activities. Moreover, such governments frequently provide services and operate facilities as well as pay for care.

d. Health services utilization and referral patterns.

e. Special population characteristics that have a distinct area dimension (e.g., Indians residing on reservations or other land areas held in trust).

f. Involvement of major prepayment plans (e.g., Blue Cross) and health maintenance organizations (HMOs).

The area, moreover, should have health facilities, manpower, and other resources adequate to provide its residents with a comprehensive range of primary and secondary health care services. It is not required, nor necessarily desirable that all highly specialized tertiary care services (e.g., burn care, cardiac surgery, kidney transplantation) be available within the area itself, though.

4. As regards nonmetropolitan areas, section 1511(a) of the Act requires—

"The boundaries of a health service area shall be established so that, in the planning and development of health services to be offered within the health service area, any economic or geographic barrier to the receipt of such services in nonmetropolitan areas is taken into account. The boundaries of health service areas shall be established so as to recognize the differences in health planning and health services development needs between nonmetropolitan and metropolitan areas."

This requirement reflects Congressional concern that nonmetropolitan areas be assured fair and equitable treatment in both the designation and redesignation of areas. It has the effect of moderating the requirements relative to population of and the range of health services and facilities in nonmetropolitan areas. The floor debate in the House in this connection is particularly relevant. For example, it was noted by Representative Alexander that health service areas in nonmetropolitan regions with "a limited range of tertiary services could properly be established with one of their health resource development objectives being increasing the range of tertiary services offered * * *" and Representative Roy observed that "While the Committee is serious about the use of 500,000 as the minimum population for health service areas, it is well within reason that the exception provided for in (the Act) * * * be applied when necessary to overcome travel time, geographic and/or economic barriers to receipt of health services in nonmetropolitan areas."

For purposes of this requirement, "nonmetropolitan areas" are defined as those areas lying outside SMSAs, and "metropolitan areas" as those within SMSAs. (By this definition about 30 percent of the U.S. population resided in nonmetropolitan areas, with 70 percent living in metropolitan areas in 1970.)

5. With respect to specialty centers, section 1511(a) states that—

"To the extent practicable, the area shall include at least one center for the provision of highly specialized health services."

The House Committee Report (p. 52) noted that this requirement "reflects the desire that the health service areas provide a self-contained, comprehensive and complete range of health services such that an individual residing in the area would rarely if ever have to leave it in order to obtain needed medical care."

The presence of a medical school, university health science center, and/or affiliated teaching, or other hospital(s) offering specialized services for patients with cancer, heart disease, kidney disease, and stroke, and the like, generally would be considered to satisfy this requirement. As noted above, however, it is not required that each area necessarily have available all of the highly specialized and more sophisticated services (e.g., major burn and trauma center). Moreover, it is recognized that some areas will not include a medical school and/or major teaching hospital. The following are among the considerations or factors to be taken into account in those instances:

a. The number and range of residency programs offered by the hospitals in the area.

b. The distances separating major medical centers and/or other highly specialized facilities. If these are great, requiring considerable travel time and cost, this would be a mitigating factor.

c. The existence of long-standing well-established referral patterns or formalized linkages with one or more major medical centers outside the area.

6. Insofar as the boundaries of other areas are concerned, section 1511(a)(4) states that—

"To the maximum extent feasible, the boundaries of the area shall be appropriately coordinated with the boundaries of areas designated under section 1152 of the Social Security Act for Professional Standards Review Organizations, existing regional planning areas, and State planning and administrative areas."

Since it is recognized that the boundaries of areas defined for different purposes cannot all be identical, the criteria for both designation and redesignation of health service areas do not require that the boundaries be identical with those for PSRO areas, regional planning areas, or State planning administrative areas.

In order to insure close coordination between the health service areas and local health systems agencies being established by this legislation and other State, regional and local health and health-related planning and administrative areas and agencies, it is important that the former—

a. Be congruent insofar as possible with one or several State planning and development districts as defined for purposes of OMB Circular A-95.

b. In the case of PSROs, to the extent practicable, (a) either a single health service area encompasses one or more PSRO areas in their entirety, or (b) several health service areas collectively encompass a single PSRO area.

c. Generally not divide locally established, functioning, and recognized COG areas (i.e., the jurisdictional areas of councils of government, regional planning agencies or development districts).

d. Follow the boundaries of local political subdivisions of general-purpose governments (e.g., counties, incorporated cities, parishes in Louisiana, townships in New England).

E. WAIVERS

The Act does provide that (1) the minimum 500,000 population requirement and/or (2) the requirement that an SMSA not be divided or split, may be waived for specific health service areas with the approval of the Secretary.

All waiver requests will be reviewed and assessed as to whether or not they meet the other requirements specified, particularly that which requires that the area "be a geographic region appropriate for the effective planning and development of health services * * *"

Therefore, requested waivers for areas with populations of less than 500,000, but more than 200,000 will be reviewed in terms of the following more specific factors:

1. Geography, including the size of the area, its natural isolation, and any major geographical barriers.

2. Population, including the extent to which it deviates from the 500,000 minimum, rate of growth in recent years, and/or low density.

3. Whether it essentially is a functional economic area (as defined by the U.S. Department of Commerce).

4. How well the area is linked to (or separated from) other areas by transportation and communication networks.

5. Whether there is a comprehensive range of primary and secondary health services within the area to meet the needs of its residents.

6. Extent to which the area is consistent with other official districts and State and county boundaries.

7. Evidence that the area has previously demonstrated a health planning capacity and community base of financial support.

8. Whether the comments of local governments, providers, the general population and others contain evidence that the area indeed is one appropriate for the effective planning and development of health services.

Requested waivers for areas with populations of less than 200,000 will be reviewed in terms of the factors enumerated above and must, in addition, meet one or more of the following criteria:

1. Have an area of 10,000 square miles or more with an average population density of less than 10 persons per square mile.
2. Be congruent with a functional economic area. (One of the functional characteristics of those areas is, that they combine labor market and labor supply, the place of work and the place of residence of the labor force. Each of the areas approaches self-sufficiency with regard to resident industries which include general and convenience retail and wholesale trade activities.)
3. By virtue of its geography and natural or physical barriers, be significantly isolated from other areas.

Waiver requests proposing an area that would split or divide an SMSA will be reviewed against the following more specific factors as well as the other requirements set forth in the Act:

1. In the case of inter-State SMSAs, the degree to which their populations are overwhelmingly in one State with only a small fraction in the other State (or States).
2. In the case of inter-State SMSAs, whether the health service area proposed is a single, statewide area for a State that otherwise might have to request a waiver to the minimum population requirement.
3. Whether the comments of local governments, providers, the general population and others contain evidence that the area indeed is one appropriate for the effective planning and development of health services.

PART 123—STATE HEALTH PLANNING AND DEVELOPMENT AGENCIES

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AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); secs. 1521-25, 1532, 1536, of the Public Health Service Act; 88 Stat. 2242-49.

SOURCE: 43 FR 10120, Mar. 10, 1978, unless otherwise noted.

Subpart A—Definitions

§ 123.1 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Conditionally designated State Agency" means an agency of the government of a State which has been designated as a State health planning and development agency on a conditional basis pursuant to section 1521(b)(2) of the Act.

(c) "Designation agreement" means an agreement entered into or renewed pursuant to section 1521 of the Act.

(d) "Fully designated State Agency" means an agency of the government of a State which has been designated as a State health planning and development agency pursuant to section 1521(b)(3) of the Act.

(e) "Governor" means the chief executive officer of a State or his designee.

(f) "Grant period" means the period with respect to which assistance is provided under Subpart C of this part.

(g) "Health care facility" means a health care facility as defined in Part 100 of this title.

(h) "Health maintenance organization" means a health maintenance organization as defined in Part 100 of this title.

(i) "Health service area" means an area designated by the Secretary pursuant to section 1511 of the Act as a health service area.

(j) "Health systems agency" means a conditionally or fully designated health systems agency designated pursuant to section 1515 of the Act and 42 CFR Part 122.

(k) "Provider of health care" means an individual—

(1) Who is a direct provider of health care (including but not limited to a physician, dentist, nurse, optometrist, podiatrist, or physician assistant) in that the individual's primary current activity is the provision of health care to individuals or the administration of facilities or institutions (including but not limited to hospitals, long-term care facilities, substance abuse treatment facilities, outpatient facilities, and health maintenance organizations) in which such care is provided and, when required by State law, the individual has received professional training in the provision of such care or in such administration and is licensed or certified for such provision or administration, or

(2) Who is an indirect provider of health care in that the individual:

(i) Holds a fiduciary position with or has a fiduciary interest in, an entity described in paragraph (i)(2)(ii) (B) or (D) of this section; (for purposes of this paragraph, a "fiduciary position or interest" as applied to any entity means a position or interest with respect to such entity affected with the character of a trust, including members of boards of directors and officers, majority shareholders, agents and attorneys); or

(ii) Receives (either directly or through his spouse) more than one-tenth of his gross annual income from any one or combination of the following:

(A) Fees or other compensation for research into or instruction in the provision of health care;

(B) Entities or associations or organizations composed of entities or individuals engaged in the provision of health care or in such research or instruction;

(C) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research into or instruction in the provision of health care; and

(D) Entities or associations or organizations composed of such entities or individuals engaged in producing drugs or such other articles; or

(iii) Is a member of the immediate family of an individual described in paragraph (i)(1) or paragraph (i)(2) (i), (ii), or (iv) of this section (for purposes of this paragraph, "immediate family" as applied to any individual includes only his parents, spouse, children, brothers and sisters who reside in the same household); or

(iv) Is engaged in issuing any policy or contract of individual or group health insurance or hospital or medical service benefits.

(l) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(m) "State" means any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa and the Northern Mariana Islands.

(n) "State health planning and development agency" or "State Agency" means an agency of State government selected by the Governor and designated in an agreement entered into pursuant to section 1521 of the Act to carry out the State's health planning and development program.

(o) "Statewide Health Coordinating Council" or "SHCC" means the body established pursuant to section 1524 of the Act to advise the State health planning and development agency.

Subpart B—Designation of State Health Planning and Development Agencies

§ 123.101 Purpose and scope.

(a) Section 1521 of the Public Health Service Act authorizes the Secretary to enter into an agreement with the Governor of each State for the designation of a State health planning and development agency for such State for the purpose of the performance within the State of the physical and mental health planning and development functions prescribed by section 1523 of the Act. Each such State health planning and development agency shall administer the State administrative program prescribed by section 1522 of the Act and shall, except as authorized under § 123.107, perform within the State the functions prescribed by section 1523 of the Act.

(b) The regulations of this subpart are applicable to agreements, pursuant to section 1521 of the Public Health Service Act, for the conditional or full designation of a State health planning and development agency for a State.

§ 123.102 Application.

The Secretary may not enter into a designation agreement under this subpart unless an application has been submitted to the Secretary for such an agreement. The application shall be submitted by a State at such time and in such form and manner as the Secretary may prescribe and shall be executed by the Governor.

§ 123.103 Contents of applications.

In addition to such other information as the Secretary may require, an approvable application shall contain:

(a) *General.* (1) A State administrative program which meets the applicable requirements of § 123.104 of this subpart.

(2) In the case of an application for designation of a State Agency on a conditional basis pursuant to section 1521(b)(2) of the Act, a proposed plan for the orderly assumption and implementation of the health planning and development functions prescribed by section 1523 of the Act and § 123.106(b) of this subpart.

(3) Assurances satisfactory to the Secretary that the agency selected by the Governor as the State Agency has the authority and resources to administer the State administrative program of the State and to carry out the health planning and development functions prescribed by section 1523 of the Act (or, in the case of an application for designation of a State Agency on a conditional basis pursuant to section 1521(b)(2) of the Act), that such agency will have such authority and

resources as may be required to implement its approved plan for the orderly assumption and implementation of such functions.

(4) In the case of an application for full designation pursuant to section 1521(b)(3) of the Act, a description of the Statewide Health Coordinating Council, which has been established for the State under section 1524 of the Act and Subpart D of this part, including a description of the manner in which the SHCC is organized and functions.

(5) A description of the proposed health planning and development activities of the State and a description of the proposed relationships between the agency selected by the Governor as the State Agency and other agencies of State government responsible for health programs of the State, including the agencies responsible for programs in alcoholism, drug abuse, mental health, and health manpower education and training (such as the Board of Higher Education or Commission on Education), and the manner in which planning for these programs will be coordinated with long-range health service needs within the State.

(6) A statement as to whether the State intends to develop a State medical facilities plan for the purpose of participating in the program authorized by Title XVI of the Act, and, if the State does so intend, a description of the manner in which the State Agency will administer or supervise the administration of such plan.

(b) *State health plan.* In addition to the requirement of paragraph (a), a State Agency must submit:

(1) A copy of its preliminary State health plan as part of its application for full designation, except that a State Agency which will have been conditionally designated for 24 months or less at the time that it enters into a full designation agreement need not submit a preliminary State health plan until it next applies for full designation; and

(2) A copy of the State health plan prepared and adopted by the SHCC as part of the State Agency's next application for full designation following the submission of the preliminary State health plan required in paragraph (b)(1) of this section, and as part of each subsequent application for designation.

§ 123.104 State administrative program.

(a) *General.* A State administrative program (hereinafter referred to as the "State Program") is a program for the performance within the State by its State Agency of the functions prescribed by section 1523 of the Act and § 123.106(b). The Secretary may not approve a State Program for a State unless it:

(1) Meets the applicable requirements of paragraph (b) of this section;

(2) Has been submitted to the Secretary by the Governor of the State as part of the application for a designation agreement; and

(3) Has been submitted to the Secretary only after the Governor of the State has afforded to members of the general public of the State a reasonable opportunity to express their views on the proposed State Program both in writing and at a public meeting sponsored by the State. At a minimum, notice of the time, place, and purpose of such meeting shall be given to members of the public at least two weeks prior to such meeting and at least 30 days prior to the date of submission of the application to the Secretary. Such notice shall also provide that a copy of the proposed State Program will be available for public inspection and copying at a specified address, and shall invite written comments thereon by members of the public. A summary of the comments made at the public meeting and copies of any written comments of members of the public shall be appended to the application.

(b) *Program requirements.* To be approved by the Secretary under this subpart, a State Program must:

(1) Provide for the performance within the State (after the designation of a State Agency and in accordance with the designation agreement) of the functions prescribed by section 1523 of the Act and § 123.106(b) and specify the State Agency of the State as the sole agency for the performance of such functions; *Provided,* That:

(i) Subject to the limitations of § 123.107, any such functions may be performed by another agency of the State government upon request of the Governor under an agreement with the State Agency; and

(ii) In the case of a State Agency designated on a conditional basis, the State Program shall provide for the performance of such functions in accordance with the plan for the orderly assumption and implementation of the health planning and development functions contained in the application;

(2) Contain or be supported by a statement by the Governor that the State Agency has under State law the authority to carry out the functions described in paragraph (b)(1) of this section, together with citations to pertinent authorizing statutes, ordinances or executive orders;

(3) Contain a complete budget for the operation of the State Agency during the period of the proposed designation agreement. Where the State Agency proposes to administer or supervise the administration of the State medical facilities plan approved by the Secretary pursuant to Title XVI of the Act, such budget shall include expenditures to be incurred in the administration of such plan;

(4) Provide for adequate consultation with the Statewide Health Coordinating Council in carrying out the State Program, and contain a description of the Statewide Health Coordinating Council's structure and relationship to the Governor and the State Agency, together with

(i) In the case of a State Agency designated on a conditional basis in a State which has no such Council at the time of such designation, a plan for the establishment of the Council in accordance with Subpart D of this Part demonstrating to the satisfaction of the Secretary that the Council will have the requisite authority; or

(ii) In the case of a fully designated agency, a statement by the Governor that there is authority under State law for such Council, together with citations to pertinent authorizing statutes, ordinances or executive orders.

(5) Set forth in such detail as the Secretary may prescribe the qualifications for personnel having responsibilities in the performance of the functions described in § 123.106(b) and the State Program and the salary structure for such personnel, and require the State Agency to have a professional staff for planning and a professional staff for development, in adequate numbers, at adequate compensation, so organized and with sufficient expertise to enable the State Agency to carry out its State Program;

(6) Provide methods of administration appropriate for the proper and efficient administration of the functions described in § 123.106(b) and the State program, including the establishment and maintenance of personnel standards on a merit basis for persons employed by the State in carrying out the State Program, *Provided*, That;

(i) Methods of personnel administration will be established and maintained in the State Agency administering the program in conformity with the Standards For a Merit System of Personnel Administration, 45 CFR Part 70, and any standards prescribed by the U.S. Civil Service Commission pursuant to section 208 of the Intergovernmental Personnel Act of 1970 modifying or superseding such standards.

(ii) Under this requirement, laws, rules, regulations, and policy statements effectuating such methods of personnel administration are a part of the State Program. Citations of applicable State laws, rules, regulations, and policies which provide assurance of conformity to the Standards in 45 CFR Part 70 must be submitted to the U.S. Civil Service Commission in accordance with 5 CFR Part 900 for determination as to adequacy. Copies of the material cited must be furnished to the Secretary or the U.S. Civil Service Commission on request.

(7) Require the State Agency to perform its functions in accordance with procedures and criteria established and published by it, which procedures and criteria shall, with respect to any reviews of proposed or existing health services, conform to the requirements of section 1532 of the Act and the applicable regulations of the Secretary;

(8) Require the State Agency to conduct its business meetings in public and give adequate notice to the public

of such meetings. For purposes of this paragraph the term "business meetings" means: (i) In the case of a State Agency headed by a collegial body, any meeting of the body to carry out the State Agency's responsibilities and functions under the Act; and (ii) In the case of a State Agency headed by an individual, any meeting of such individual with persons directly affected by a State Agency review (as defined for the purpose of providing written notification of the beginning of the review), concerning a State Agency review conducted pursuant to section 1523 of the Act during the course of such review;

(9) Require the State Agency to adopt a policy for making its records and data available to the general public in accordance with the requirements of § 123.109;

(10) Provide that the State Agency will enter into a written agreement with each agency or organization in the State which has entered into an agreement with the Secretary under section 306(e) of the Act so as to assure that the State Agency has the data needed on a timely basis for health planning and resources development in the State, and that such data will be made available to all health systems agencies designated for health service areas located in whole or in part within the State;

(11) Require providers of health care doing business in the State to make to the State Agency such statistical and other reports of information related to health and health care as the State Agency finds necessary to the performance of its functions under this subpart, and make such reports available to the health systems agencies for the respective health service areas in which such providers are located. For purposes of this paragraph, "providers of health care" include, at a minimum, health care facilities and health maintenance organizations.

(12) Provide, in accordance with methods and procedures approved by the Secretary, for the evaluation, at least annually, of the performance by the State Agency of its functions and of their economic effectiveness;

(13) Provide that the State Agency will from time to time, and in any event not less often than annually, review the State Program and submit to the Secretary required modifications;

(14) Require the State Agency to make such reports, in such form and containing such information concerning its structure, operations, performance of functions, and other matters as the Secretary may from time to time require, and keep such records and afford such access thereto as the Secretary may find necessary to verify such reports;

(15) Require the State Agency to provide for fiscal control and fund accounting procedures, consistent with applicable requirements of Subpart C of this part, as the Secretary may require to assure proper disbursement of, and accounting for, funds received by the State Agency under section 1525 of the Act;

(16) Permit the Secretary and the Comptroller General of the United States, or their representatives, to have access for the purpose of audit and examination to any books, documents, papers, and records of the State Agency pertinent to the disposition of amounts received from the Secretary under section 1525 of the Act; and

(17) Provide that if the State Agency makes a decision in the performance of a function under section 1523(a) (3), (4), (5) or (6) or Title XVI of the Act which is inconsistent with a recommendation made under section 1513 (f), (g) or (h) of the Act by a health systems agency for a health service area located in whole or in part within the State—

(i) Such decision (and the record upon which it was made) shall, upon request of such health systems agency, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State health planning and development agency or the Statewide Health Coordinating Council) designated by the Governor, and

(ii) The decision of the reviewing agency shall for purposes of Titles XV and XVI of the Act be considered the decision of the State Agency.

§ 123.105 Conditional Designation Agreements.

In accordance with section 1521 (b)(2) of the Act and this subpart, the Secretary may enter into an agreement (hereinafter referred to as the conditional Designation Agreement) with a Governor for the Designation of an agency (selected by the Governor) of the government of that State as the State Agency on a conditional basis with a view to determining the State Agency's ability at the end of the period of its conditional designation to meet the requirements and perform the functions of a fully designated State Agency under the Act and this subpart. Such agreement shall provide that:

(a) The agency is designated as the conditionally designated State Agency for the State for a term not to exceed 12 months, beginning on a date specified in the agreement, except that the term of the agreement may be extended by the Secretary at the request of the Agency for the sole purpose of closing out the activities of the State Agency. In no case, however, may the entire period of conditional designation exceed 36 months.

(b) During the period of conditional designation, the Secretary shall require the State Agency to perform only such of the functions prescribed by section 1523 of the Act and § 123.106(b) as he determines such State Agency to be capable of performing; *Provided*, That the State Agency must perform at least the functions described in § 123.106(b) (1), (2), and (5) and, immediately upon the establishment of a Statewide Health Coordinating Council for the State, the functions described in § 123.106 (b)(3).

(c) During the period of conditional designation the numbers and types of requirements and functions may, in accordance with paragraph (b) of this section, be progressively increased as the State Agency, in the judgment of the Secretary, becomes capable of added responsibility.

(d) The State Agency shall meet the requirements of the Act, this subpart, and any additional conditions set forth in the Conditional Designation Agreement.

§ 123.106 Full Designation Agreements.

In accordance with section 1521 (b)(3) of the Act and this subpart, the Secretary may enter into an agreem nt (hereinafter referred to as the Full Designation Agreement) with a Governor for the designation of an agency (selected by the Governor) of that State as the State Agency for the State. Such Full Designation Agreement shall provide that:

(a) The agency is designated as the State Agency for the State for a term not to exceed 12 months, beginning on a date specified in the agreement.

(b) The State Agency shall, subject to § 123.107 perform within the State the following functions:

(1) Conduct the health planning activities of the State and implement those parts of the State health plan prepared by the Statewide Health Coordinating Council pursuant to section 1524(c)(2) of the Act and Subpart D of this part and, except for States to which Subpart F of this part is applicable, the plans of the health systems agencies within the State which relate to the government of the State;

(2) In accordance with a schedule established by the Statewide Health Coordinating Council of the State, prepare, review, and revise as necessary (but at least annually), and submit to the Statewide Health Coordinating Council of the State for approval or disapproval and for use in developing the State health plan referred to in paragraph (b)(1) of this section, a preliminary State health plan which shall, except as provided in Subpart F of this Part, be made up of the Health Systems Plans (hereinafter referred to as "HSP's") of the health systems agencies within the State. Such preliminary plan may, as found necessary by the State Agency, contain revisions of such HSP's to achieve their appropriate coordination or to deal more effectively with statewide health needs.

(3) Assist the Statewide Health Coordinating Council of the State, through the payment of its operating expenses and the provision of adequate staff support and appropriate training programs in health resources planning and development for members of the Council, in the review of

the State medical facilities plan required under section 1603 of the Act, and in the performance of its functions generally;

(4) (i) Serve as the designated planning agency of the State for purposes of section 1122 of the Social Security Act and in accordance with 42 CFR Part 100, if the State has entered into an agreement with the Secretary pursuant to such section 1122; and

(ii) Administer a State certificate of need program which meets the requirements of Subpart E of this part; *Provided*, That the requirement of clause (b)(4)(ii) hereof shall not apply to a State Agency of a State until the expiration of the first regular session of the legislature of such State which begins after January 4, 1975;

(5) After consideration of recommendations submitted by Health Systems Agencies under section 1513(f) of the Act respecting new institutional health services proposed to be offered within the State, make findings as to the need for such services in accordance with section 1532 of the Act and Subpart E of this part;

(6) Review on a periodic basis (but not less often than every five years), in accordance with section 1532 of the Act and applicable regulations of the Secretary, all institutional health services being offered in the State and, after consideration of recommendations submitted by health systems agencies pursuant to 42 CFR 122.107(c)(15) respecting the appropriateness of such services, make public its findings; *Provided*, That such findings with respect to any health service area in the State shall be made not more than one year following the date on which the health systems agency for such area submits its recommendations to the State Agency.

(c) The State Agency shall meet the requirements of the Act, this subpart, and any additional conditions set forth in the Full Designation Agreement.

§ 123.107 Performance of functions by other than the State Agency.

(a) Notwithstanding any other provision of this subpart, any function described in § 123.106(b) of this subpart may be performed by another agency of the State government upon request of the Governor under an agreement with the State Agency satisfactory to the Secretary except that the functions described in § 123.106(b)(4) must be performed by the same agency of the State.

(b) Any agreement entered into by the State Agency for the performance of one or more functions described in § 123.106(b) of this subpart by another agency of the State must at a minimum:

(1) Specify which other agency will perform the function, which function it will perform, and that the other agency will perform all the activities relating to the function;

(2) Provide that the other agency will perform the function in accordance with the appropriate requirements of the State Program and in compliance with the relevant provisions of the Act and applicable regulations of the Secretary including those set forth in this part;

(3) Set forth the manner in which the budget, staff, and activities of the other agency in the performance of the function will relate to the activities of the State Agency;

(4) Provide that the other agency will consult and coordinate with the State Agency and the SHCC on the performance of the function and provide information to the State Agency and the SHCC on the performance of the function;

(5) Set forth the manner in which the other agency will relate to the health systems agencies whose health service areas are located in whole or in part within the State;

(6) Set forth the conditions under which the agreement may be terminated by either agency; and

(7) Set forth the conditions under which the agreement may be renewed.

§ 123.108 Renewal and termination of agreements.

(a) *Conditionally designated State Agencies*—(1)*Renewal.* A Conditional Designation Agreement may, at the option of the Secretary and based upon the Secretary's review of the State Agency's performance and its application for renewal, be renewed for an additional term not to exceed 12 months, but in no case may the total period of conditional designation of a State Agency exceed 36 months. Where the Secretary determines not to renew such agreement, the Governor will be notified in writing of the reasons for such determination.

(2) *Termination.* A Conditional Designation Agreement may be terminated by the Governor prior to the expiration of its term upon 90 days written notice to the Secretary which shall set forth the reasons for such termination and its effective date. The Secretary may terminate the Conditional Designation Agreement prior to the expiration of its term upon his determination, after having given the Governor at least 90 days written notice of the State Agency's deficiencies and the corrective actions required and an opportunity for a hearing before an officer or employee of the Department designated for such purpose by the Secretary, that the State Agency is not complying with the provisions of the Agreement or is incapable of progressively assuming more functions and responsibilities.

(b) *Fully designated agencies*—(1) *Renewal.* A Full Designation Agreement may be renewed for a period not to exceed 12 months, upon the application by the Governor for renewal, if upon review by the Secretary (as provided in section 1535 of the Act) he determines that the State Agency has fufilled, in a satisfactory manner, the functions of a State Agency as prescribed by section 1523 of the Act and the applicable provisions of this subpart. A determination by the Secretary not to renew the Agreement will be made only after he has provided the Governor with written notice of the reasons for such failure to renew and of the opportunity for a hearing before an officer or employee designated for such purpose by the Secertary.

(2) *Termination.* A Full Designation Agreement may be terminated by the Governor prior to the expiration of its term upon 90 days written notice to the Secretary which will set forth the reasons for such termination and its effective date. The Agreement may be terminated by the Secretary prior to the expiration of its term if he determines, after having given the Governor at least 90 days written notice of the State Agency's deficiencies and the corrective actions required and an opportunity for a hearing before an officer or employee of the Department designated for such purpose by the Secretary, that the State Agency is not complying with or effectively carrying out the provisions of the Agreement.

§ 123.109 Access of the public to State Agency records and data.

(a) Each State Agency shall adopt a policy for making its records and data available to the public for inspection and copying in accordance with sections 1522(b)(6)(C) and 1532(b)(10) of the Act, which shall include a procedure for the submission of requests to the agency by members of the public, the agency's procedure for handling such requests, and a uniform fee schedule for copying such material which shall be limited to reasonable costs. For purposes of this paragraph, "records and data" include publications, brochures, pamphlets, punch cards, magnetic tapes, minutes, staff manuals, slides, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by the State Agency in connection with the performance of the agency's functions under its designation agreement and retained by the agency as evidence of the agency's function, policies, decisions, procedures, operations, programs, or other activities.

(b) Each State Agency is required to maintain and make available for public inspection and copying an index of the records and data of the agency and must publish a notice that a policy for making information available to the public has been established setting forth the policy adopted pursuant to paragraph (a) of this section. The notice must contain a statement that the full policy is available for public inspection and copying. Where subsequent to the publication of such notice the State Agency substantially revises its policy (which must remain consistent with paragraph (a) of this section) for making information available to the public the State Agency must publish a notice that such revisions have been made.

Subpart C—Grants to State Health Planning and Development Agencies

§ 123.201 Applicability.

The regulations of this subpart are applicable to grants under section 1525 of the Public Health Service Act (42 U.S.C. 300m-4) to State health planning and development agencies designated under section 1521 of the Public Health Service Act (42 U.S.C. 300m) to assist them in meeting the costs of their operation, including costs incurred in the administration of the State medical facilities plan under Title XVI of the Act.

§ 123.202 Eligibility.

Any conditionally or fully designated State Agency is eligible for a grant under this subpart.

§ 123.203 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an officer or employee of the State officially authorized to act for the applicant agency and to assume on behalf of the agency the obligations imposed by the Act, the regulations of this subpart, and any additional terms or conditions of the grant.[1]

(b) The application shall contain the following:

(1) A full and complete budget (i) of expenditures to be incurred by the applicant agency in carrying out its approved State administrative program in accordance with section 1522 of the Act and the terms and conditions of the designation agreement entered into by the Secretary and the Governor of the State pursuant to Subpart B of this part (including expenditures to be incurred in assisting the Statewide Health Coordinating Council in the performance of its functions), and (ii) where the State Agency is administering or supervising the administration of the State medical facilities plan approved by the Secretary pursuant to Title XVI of the Act, of expenditures to be incurred in the administration of such plan.

(2) An assurance satisfactory to the Secretary that the State Agency will expend in performing the functions prescribed by section 1523 of the Act during the fiscal year for which the grant is sought an amount of funds from non-Federal sources which is at least as great as the average amount of funds from non-Federal sources expended for such purposes (excluding expenditures of a non-recurring nature) in the three fiscal years immediately preceding the fiscal year for which the grant is sought, by the State for which such State Agency has been designated. Such assurance shall be supported by the following:

(i) An itemized statement showing the amount of funds from non-Federal sources expended by the State for carrying out functions described in section 1523 of the Act in each of the three fiscal year immediately preceding the fiscal year for which the grant is sought, excluding expenditures of a non-recurring nature; and

(ii) A description of the amount and sources of non-Federal funds which will be expended by the State Agency in carrying out the functions described in section 1523 of the Act under the designation agreement during the grant period; and

(3) A statement of the amount of grant funds requested.

§ 123.204 Grant award.

(a) The Secretary will award a grant under this subpart to each agency which

(1) Is designated as a State Agency under a designation agreement;

(2) Has provided the assurance required by § 123.203(b)(2); and

(3) Otherwise meets the applicable requirements of the Act and of this subpart.

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[1] Applications and instructions may be obtained from the Regional Health Administrator in the Regional Office of the Department of Health and Human Services for the region in which the State is located.

section) for making information available to the public the State Agency must publish a notice that such revisions have been made.

Subpart C—Grants to State Health Planning and Development Agencies

§ 123.201 Applicability.

The regulations of this subpart are applicable to grants under section 1525 of the Public Health Service Act (42 U.S.C. 300m-4) to State health planning and development agencies designated under section 1521 of the Public Health Service Act (42 U.S.C. 300m) to assist them in meeting the costs of their operation, including costs incurred in the administration of the State medical facilities plan under Title XVI of the Act.

§ 123.202 Eligibility.

Any conditionally or fully designated State Agency is eligible for a grant under this subpart.

§ 123.203 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an officer or employee of the State officially authorized to act for the applicant agency and to assume on behalf of the agency the obligations imposed by the Act, the regulations of this subpart, and any additional terms or conditions of the grant.[1]

(b) The application shall contain the following:

(1) A full and complete budget (i) of expenditures to be incurred by the applicant agency in carrying out its approved State administrative program in accordance with section 1522 of the Act and the terms and conditions of the designation agreement entered into by the Secretary and the Governor of the State pursuant to Subpart B of this part (including expenditures to be incurred in assisting the Statewide Health Coordinating Council in the performance of its functions), and (ii) where the State Agency is administering or supervising the administration of the State medical facilities plan approved by the Secretary pursuant to Title XVI of the Act, of expenditures to be incurred in the administration of such plan.

(2) An assurance satisfactory to the Secretary that the State Agency will expend in performing the functions prescribed by section 1523 of the Act during the fiscal year for which the grant is sought an amount of funds from non-Federal sources which is at least as great as the average amount of funds from non-Federal sources expended for such purposes (excluding expenditures of a non-recurring nature) in the three fiscal years immediately preceding the fiscal year for which the grant is sought, by the State for which such State Agency has been designated. Such assurance shall be supported by the following:

(i) An itemized statement showing the amount of funds from non-Federal sources expended by the State for carrying out functions described in section 1523 of the Act in each of the three fiscal year immediately preceding the fiscal year for which the grant is sought, excluding expenditures of a non-recurring nature; and

(ii) A description of the amount and sources of non-Federal funds which will be expended by the State Agency in carrying out the functions described in section 1523 of the Act under the designation agreement during the grant period; and

(3) A statement of the amount of grant funds requested.

§ 123.204 Grant award.

(a) The Secretary will award a grant under this subpart to each agency which

(1) Is designated as a State Agency under a designation agreement;

(2) Has provided the assurance required by § 123.203(b)(2); and

(3) Otherwise meets the applicable requirements of the Act and of this subpart.

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[1] Applications and instructions may be obtained from the Regional Health Administrator in the Regional Office of the Department of Health and Human Services for the region in which the State is located.

regulations of the Secretary, for monitoring and enforcing assurances provided to the State by hospitals and other medical facilities which receive Federal assistance under Title VI of the Act, and for carrying out the State administrative program in accordance with Title XV of the Act, the applicable provisions of this Part, the designation agreement, any additional terms and conditions of the grant award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Funds granted pursuant to this subpart shall be available for obligation only during the period of the State Agency's designation agreement.

§ 123.207 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular, section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80). Nor shall any person be denied employment in or by the program or activity supported by a grant made pursuant to this subpart on the grounds of age, creed, sex, or marital status.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing section 504, which is applicable to grants made under this subpart, has been issued by the Secretary (45 CFR Part 84).

§ 123.208 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart.

(b) *Accounting for non-Federal funds.* The agency shall account for all non-Federal funds expended during the grant period in carrying out the approved activities in accordance with procedures prescribed by the Secretary.

§ 123.209 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart.

§ 123.210 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of the award when in his judgment such conditions are necessary to assure or protect advancement of the approved activity, the interests of the public health, or the conservation of grant funds.

Subpart D—Statewide Health Coordinating Councils

§ 123.301 Purpose and scope.

Section 1524 of the Public Health Service Act provides that each State health planning and development agency shall be advised by a Statewide Health Coordinating Council. The regulations of this subpart are applicable to the establishment and operation of SHCC's.

§ 123.302 Establishment.

A SHCC may not be established in a State until health systems agencies have been designated for one-half or more of the health service areas which are located in whole or in part in the State.

§ 123.303 Composition.

Except as authorized by § 123.503, a SHCC shall be composed in the following manner:

(a) A SHCC shall have no fewer than 16 representatives appointed by the Governor of the State from lists of at least five nominees submitted to the Governor by each of the health systems agencies designated for health service areas which fall, in whole or in part, within the State.

(1) Each such health systems agency shall be entitled to the same number of representatives on the SHCC.

(2) Each such health systems agency shall be entitled to at least two representatives on the SHCC.

(3) Of the representatives of any health systems agency, not less than one-half shall be individuals who are consumers of health care and who are not providers of health care.

(4) Each such health systems agency shall submit to the Governor a list of nominees numbering at least twice the number of representatives to which the health systems agency is entitled, or five, whichever is greater; except that any health systems agency may, at its option and if the Governor so requests, submit a lesser number of nominees.

(b) In addition to the appointments made under paragraph (a) of this section, the Governor may appoint such persons (including State officials, public elected officials, and other representatives of governmental authorities within the State) to serve on the SHCC as he deems appropriate; except that

(1) The number of persons appointed to the SHCC under this paragraph may not exceed 40 per centum of the total membership of the SHCC; and

(2) A majority of the persons appointed by the Governor under this paragraph shall be consumers of health care who are not providers of health care.

(c) Not less than one-third of the providers of health care who are members of the SHCC shall be direct providers of health care.

(d) Where two or more hospitals or other health care facilities of the Veterans Administration are located in a State, the SHCC for such State shall, in addition to the other members appointed pursuant to this section, include, as an ex officio member, an individual whom the Chief Medical Director of the Veterans Administration shall have designated as a representative of such facilities. Such individual shall be considered a direct provider of health care for purposes of paragraph (c) of this section.

§ 123.304 Chairman and terms of membership.

(a) The SHCC shall select from among its members a chairman.

(b) The terms of SHCC members shall be of fixed length.

§ 123.305 Statewide Health Coordinating Council rules.

The SHCC shall be governed by written rules which set forth the policies and procedures for the functioning of the SHCC and which, at a minimum:

(a) Provide that the SHCC will meet not less than once in each calendar quarter for the purpose of performing one or more of the functions described in § 123.306;

(b) Provide that all business meetings of the SHCC shall be open to the public. For purposes of this paragraph, "business meetings" are meetings at which a SHCC acts to carry out its functions under the Act;

(c) Set forth the manner in which members of the SHCC will be selected and replaced, which shall be consistent with the requirements of section 1524 of the Act and which shall include provisions for (1) removal of members for good cause only; and (2) replacement of members in the event of resignation, death, or removal; and

(d) Set forth requirements relating to conflict of interest, which shall be designed to preclude use of membership on the SHCC for purposes which are, or give appearances of being, motivated by private gain on the part of any individual.

§ 123.306 Functions.

A SHCC shall perform the following functions:

(a) Review annually the Health Systems Plan ("HSP") and Annual Implementation Plan ("AIP") of each health systems agency of a health service area located in whole or in part within the State and report to the Secretary, for purposes of his review under section 1535(c) of the Act, its comments on such HSP and AIP, at such times and in such form and manner as the Secretary may direct. The SHCC, after consultation with the State Agency and health systems agencies located in whole or in part within the State, shall establish a uniform analytical approach and format for HSPs.

(b) Prepare, and review and revise as necessary (but at least annually), a State health plan which shall be made up of the HSP's of the health systems agencies within the State. Such plan may, as found necessary by the SHCC, contain revisions of such HSP's to achieve their appropriate coordination or to deal more effectively with statewide health needs. Where the State health plan does contain revisions of an HSP, the SHCC shall return the affected HSP to the appropriate health systems agency together with a statement of the revisions of the HSP that must be made by the agency.

(1) In the preparation and revision of the State health plan, the SHCC shall review and consider the preliminary State health plan submitted by the State Agency under section 1523(a)(2) of the Act and § 123.106(b)(2) and shall conduct a public hearing on the plan as proposed by the SHCC and shall give interested persons an opportunity to submit their views orally and in writing.

(i) Not less than 30 days prior to any such hearing, the SHCC shall publish in at least two newspapers of general circulation in the State a notice of its consideration of the proposed plan, the time and place of the hearing, the place at which interested persons may consult the plan in advance of the hearing, and the place and period during which to direct written comment to the SHCC on the plan.

(ii) At least 15 days prior to such publication, the SHCC shall provide a copy of the plan to the Governor for purposes of his review and comment.

(2) At such time and in such form and manner as the Secretary may prescribe, the SHCC shall provide to the Secretary a copy of its current State health plan.

(c) Following adoption of the State health plan, as part of its coordination of AIPs review the AIP of each health systems agency located in whole or in part within the State and recommend revisions to the AIP to ensure consistency with revisions of the HSP required by the SHCC.

(d) Review annually the budget of each health systems agency located in whole or in part within the State and report to the Secretary, for purposes of his review under section 1535(a) of the Act, is comments on such budget, at such time and in such form and manner as the Secretary may direct.

(e) Review applications submitted by such health systems agencies (or, in the case of the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, American Samoa, the Northern Mariana Islands, and any other State which has been determined by the Secretary to meet the requirements of section 1536(a) of the Act, by the State Agencies of such States) for grants under sections 1516 and 1640 of the Act and report to the Secretary, at such time and in such form and manner as the Secretary may direct its comments on such applications.

(f) Advise the State Agency generally on the performance of its functions, including review and comment to the State Agency on its application for designation prior to its submission to the Secretary.

(g) Review annually and approve or disapprove any State plan and any application (and any revision of a State plan or application) submitted to the Secretary as a condition to the receipt of Federal funds, made available under allotments, in accordance with section 1524(c)(6) of the Act and applicable regulations of the Secretary.

(h) Review and approve or disapprove the State medical facilities plan prepared by the State Agency pursuant to section 1603 of the Act, on the basis of whether such State medical facilities plan is consistent with the State health plan prepared in accordance with paragraph (b) of this section.

(i) Where applicable, review and comment on State Agency actions described in § 123.502(a)(2) before such actions become final.

Subpart E—Certificate of Need Reviews

AUTHORITY: Section 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sections 1501-1532 of the Public Health Service Act, 93 Stat. 592-630 (42 U.S.C. 300k-1—300n-1).

SOURCE: 45 FR 69745, Oct. 21, 1980, unless otherwise noted.

§ 123.401 Definitions.

In addition to the terms defined in Subpart A of this part, as used in this subpart:

The term "affected persons" includes, at a minimum, the applicant; the health systems agency for the health service area in which the proposed project is to be located; health systems agencies serving contiguous health service areas or located within the same standard metropolitan statistical area; any person residing within the geographic area served or to be served by the applicant; any person who regularly uses health care facilities within that geographic area; health care facilities and health maintenance organizations (HMOs) located in the health service area in which the project is proposed to be located which provide services similar to the services of the facility under review; health care facilities and HMOs which, prior to receipt by the agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; third party payers who reimburse health care facilities for services in the health service area in which the project is proposed to be located; and any agency which establishes rates for health care facilities or HMOs located in the health service area in which the project is proposed to be located.

The term "capital expenditure" means an expenditure made by or on behalf of a health care facility which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance.

The term "expenditure minimum for capital expenditures" means $150,000 for the twelve-month period beginning October 1, 1979, and for each twelve-month period thereafter, $150,000 or, at the discretion of the State, the figure in effect for the preceding twelve-month period, adjusted to reflect the change in the preceding twelve-month period in the Department of Commerce Composite Construction Cost Index.

The term "expenditure minimum for annual operating costs" means $75,000 for the twelve-month period beginning October 1, 1979, and for each twelve-month period thereafter, $75,000 or, at the discretion of the State, the figure in effect for the preceding twelve-month period, adjusted to reflect the change in the preceding twelve-month period in the Department of Commerce Composite Construction Cost Index.

The term "health" includes physical and mental health.

The term "health care facility" means hospitals, skilled nursing facilities, kidney disease treatment centers (including freestanding hemodialysis units), intermediate care facilities, rehabilitation facilities, and ambulatory surgical facilities, but does not include Christian Science sanatoriums operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts. Further:

(1) The term "hospital" means an institution which primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. This term also includes psychiatric and tuberculosis hospitals.

(2) The term "psychiatric hospital" means an institution which primarily provides to inpatients, by or under the supervision of a physician, specialized services for the diagnosis, treatment

and rehabilitation of mentally ill and emotionally disturbed persons.

(3) The term "tuberculosis hospital" means an institution which primarily provides to inpatients, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis.

(4) The term "skilled nursing facility" means an institution or a distinct part of an institution which primarily provides to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(5) The term "intermediate care facility" means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility provides, but who because of their mental or physical condition require health related care and services (above the level of room and board).

(6) The term "rehabilitation facility" means an inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision.

(7) The term "ambulatory surgical facility" means a facility, not a part of a hospital, which provides surgical treatment to patients not requiring hospitalization. The term does not include the offices of private physicians or dentists, whether for individual or group practice.

EXPLANATORY NOTE: Where a hospital is part of a larger institution, such as a university, the components of the larger institution (e.g., a component conducting medical research) not related to the hospital need not be considered part of the hospital, whether or not the hospital is a distinct legal entity. Similarly, where there is a legal entity, the primary activity of which is operating a hospital, but which also operates a distinct research component, the research component need not be considered part of the hospital. In these cases the component conducting medical research that is distinct from the hospital and that neither provides inpatient services nor uses revenues derived from patient charges at the hospital to finance its operations need not be considered part of the hospital. (Also see the explanatory note following § 123.404(a)(1) for a discussion of circumstances in which capital expenditures by the non-hospital components are subject to review.)

The term "health maintenance organization" or "HMO" means a public or private organization organized under the laws of any State, (1) which is a qualified health maintenance organization under section 1310(d) of the Act, or (2) which:

(i) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services, and out of area coverage; and

(ii) Is compensated (except for copayments) for the provision of the basic health care services listed in paragraph (2)(i) of this definition to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and

(iii) Provides physicians' services primarily (A) directly through physicians who are either employees or partners of the organization, or (B) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

The term "health services" means clinically related (i.e., diagnostic, treatment, or rehabilitative) services, and includes alcohol, drug abuse, and mental health services.

The term "major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used to provide medical and other health services and which costs more than $150,000. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory is independent of a physician's office and a hospital and has been determined under title XVIII of the Social Security Act to meet the requirements of paragraphs (10) and (11) of section 1861(s) of that Act. In determining whether medical equipment costs more than $150,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to acquiring the equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

NOTE: The acquisition of equipment which does not meet the definition of major medical equipment and thus is not subject to review under § 123.404(a)(4), will be subject to review if it meets any other requirement under § 123.404(a).

The term "person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies, and insurance companies), a State, a political subdivision or an instrumentality (including a municipal corporation) of a State, or any legal entity recognized by the State.

The term "physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by a State.

§ 123.402 Purpose and applicability.

(a) Section 1523(a)(4)(B) of the Act requires each State health planning and development agency (State Agency) to administer a State certificate of need program which (1) applies to the obligation of capital expenditures within the State, the offering within the State of new institutional health services, and the acquisition of major medical equipment, and (2) is consistent with regulations of the Secretary. This subpart sets forth the requirements and standards that a State certificate of need program must meet. A State certificate of need program may include additional provisions not inconsistent with the requirements of this subpart.

(b) Section 1532(a) of the Act requires that in performing its review functions under section 1523(a)(4)(B) of the Act, each State Agency shall (except to the extent approved by the Secretary) follow procedures, and apply criteria, developed and published by the State Agency in accordance with regulations of the Secretary. This subpart sets forth requirements respecting these procedures and criteria.

§ 123.403 General.

(a) Each State Agency shall administer within the State a certificate of need program meeting the requirements of this subpart.

(b) Only the State Agency (or the appropriate administrative or judicial review body) may issue, deny or withdraw certificates of need, grant exemptions from certificate of need reviews, or determine that certificate of need reviews are not required.

(c) In issuing or denying certificates of need or in withdrawing certificates of need, the State Agency shall take into account recommendations made by health systems agencies under Subpart D of Part 122 of this title.

(d) Each decision of the State Agency (or the appropriate administrative or judicial review body) to issue a certificate of need must be consistent with the State health plan, except in emergency circumstances that pose an imminent threat to public health.

(e) Each decision of a State Agency to issue, deny, or withdraw a certificate of need must be based (1) on the review by the State Agency conducted in accordance with procedures and criteria it has adopted under this subpart, and (2) on the record of the administrative proceedings held on the application for the certificate or the State Agency's proposal to withdraw the certificate. Each decision of a State Agency to grant or deny an exemption under § 123.405 (HMOs) must be made in accordance with the State Agency's procedures for reviewing applications for exemptions and must be based solely on the record of the administrative proceedings held on the application.

§ 123.404 Scope of certificate of need review programs.

(a) *Required coverage.* The State certificate of need program must apply to the obligation of capital expenditures, the offering of new institutional health services, and the acquisition of major medical equipment. For purposes of this subpart, "the obligation of capital expenditures, offering of new institutional health services, and acquisition of major medical equipment" means the following:

(1) *Capital expenditures that exceed the expenditure minimum.* The obligation by or on behalf of a health care facility of any capital expenditure (other than to acquire an existing health care facility) that exceeds the expenditure minimum for capital expenditures (or any lesser amount the State may specify). The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort and consulting and other services) essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds the expenditure minimum. As to the obligation of a capital expenditure to acquire an existing health care facility, see paragraph (a)(5) of this section.

EXPLANATORY NOTE: Expenditures by a component of a larger institution, such as a university, which is distinct from a separate health care facility component, such as the university's hospital, need not be viewed as being "by a health care facility" for purposes of this section. Thus, a capital expenditure by a university medical school that is a distinct component of the university need not be considered to be "by" the hospital of the university. In finding that the medical school is distinct, the State Agency should find at least that the revenues derived from patient charges at the hospital of the university are not used for operating expenses of the medical school. If a capital expenditure exceeds the expenditure minimum, for it to be required to be subject to review, the State Agency must find that it is "on behalf of" a health care facility. Such an expenditure is also required to be subject to review if it is for the acquisition of major medical equipment and meets the conditions set forth in § 123.404(a)(4) of this subpart. The same analysis would apply to a distinct research component of a legal entity, the primary activity of which is operating a hospital.

(2) *Bed capacity.* The obligation of any capital expenditure by or on behalf of a health care facility which—(i) increases or decreases the total number of beds, (ii) redistributes beds among various categories, or (iii) relocates beds from one physical facility or site to another—by ten beds or ten percent, whichever is less, in any two-year period.

(3) *Health services.* (i) The obligation of any capital expenditure by or on behalf of a health care facility which is associated with (A) the addition of a health service which was not offered by or on behalf of the facility within the previous twelve months, or (B) the termination of a health service which was offered in or through the facility; or

(ii) The addition of a health service which is offered by or on behalf of the health care facility which was not offered by or on behalf of the facility within the twelve-month period before the month in which the service would be offered, and which entails annual operating costs of at least the expenditure minimum for annual operating costs.

(4) *Major medical equipment.* (i) The acquisition by any person of major medical equipment that will be owned by or located in a health care facility; or

(ii) The acquisition by any person of major medical equipment not owned by or located in a health care facility, if (A) the notice of intent required by § 123.406(a) is not filed in accordance with that paragraph, or (B) the State Agency finds, within 30 days after the date it receives a notice in accordance with § 123.406(a), that the equipment will be used to provide services for inpatients of a hospital.

(iii) An acquisition of major medical equipment need not be reviewed if it will be used to provide services to inpatients of a hospital only on a temporary basis in the case of (A) a natural disaster, (B) a major accident, or (C) equipment failure.

(iv) A State program may cover major medical equipment not owned by or located in a health care facility beyond the minimum coverage required by this subparagraph; however, after September 30, 1982, the certificate of need program of a State may not be changed to include additional requirements for coverage of this equipment.

(5) *Acquisitions of health care facilities.* (i) Except as provided in § 123.405(b) (HMOs), the obligation of a capital expenditure by any person to acquire an existing health care facility (A) if the notice of intent required at § 123.406(b) is not filed in accordance with that paragraph, or (B) if the State Agency finds, within 30 days after the date it receives a notice in accordance with § 123.406(b), that the services or bed capacity of the facility will be changed in being acquired.

(ii) Each State Agency shall specify, for purposes of the preceding sentence, what activities result in a change in the services or bed capacity of a health care facility; however, these activities must include at least (A) a change in bed capacity as described in paragraph (a)(2) of this section, (B) the addition of a health service which was not offered by or on behalf of the facility within the previous twelve months, and (C) the termination of a health service which was offered by or on behalf of the facility.

(b) *Leases, donations, and transfers.* An acquisition by donation, lease, transfer, or comparable arrangement must be reviewed if the acquisition would be subject to review under paragraph (a) of this section if made by purchase. An acquisition for less than fair market value must be reviewed if the acquisition at fair market value would be subject to review under paragraph (a) of this section.

(c) *Incurring an obligation.* No person may incur an obligation for a capital expenditure that is subject to review under paragraphs (a)(1), (a)(2), (a)(3)(i), or (a)(5) of this section without obtaining a certificate of need for the capital expenditure. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility: (1) When a contract, enforceable under State law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset; or (2) When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or (3) In the case of donated property, on the date on which the gift is completed under applicable State law.

NOTE: A State may consider an obligation for a capital expenditure which is contingent upon issuance of a certificate of need not to be incurred until the certificate of need is issued.

(d) *Subsequent reviews.*—(1) *Capital expenditures.* The State program must provide as follows: A proposed change in a project associated with a capital expenditure for which the State Agency has previously issued a certificate of need will require review if the change is proposed within one year (or any longer period established under the State Program) after the date the activity for which the expenditure was approved is undertaken. (As an illustration, where a hospital receives approval to construct a new wing for its facility, the hospital will "undertake the activity" when it begins to provide services in the wing.) This subparagraph applies to changes associated with capital expenditures that were subject to review under paragraph (a)(1), (a)(2) or (a)(3)(i) of this section. A review is required under this paragraph whether or not a capital expenditure is associated with the proposed change. A "change in a project" shall include, at a minimum, any change in the bed capacity of a facility as described in paragraph (a)(2) of this section, and the addition or termination of a health service.

EXPLANATORY NOTE: Examples that illustrate coverage required by this paragraph are as follows: (1) A certificate of need is obtained for the obligation of a capital expenditure which results in the addition of ten psychiatric beds. Within one year, those beds are proposed to be converted to pediatric beds. Certificate of need review is required for the conversion, regardless of whether this later activity is associated with a capital expenditure. (2) A certificate of need is obtained for the obligation of a capital expenditure which results in the addition of a new psychiatric service. Within one year, this service is proposed to be converted to a new pediatric service. Certificate of need review is required, regardless of whether a capital expenditure associated with the new service will be incurred or annual operating costs of at least the expenditure minimum will result.

(2) *Major medical equipment.* If a person acquires major medical equipment not located in a health care facility without a certificate of need and proposes at any time to use that equipment to serve inpatients of a hospital the proposed new use must be reviewed unless the use is one described in paragraph (a)(4)(iii) of this section.

(3) *Existing facilities.* If a person acquires an existing health care facility without a certificate of need and proposes to change within one year after the acquisition (or any longer period of time established under the State program) the services or bed capacity of the facility, the proposed change must be reviewed if it would have required review under paragraph (a)(5) of this section originally.

(e) *Dissemination of scope of coverage.* Before reviewing any project not previously within the scope of the State program's coverage, each State Agency shall disseminate to all health systems agencies, health care facilities, and HMOs within the State, and shall publish in one or more newspapers of general circulation in the State, a description of the scope of coverage of its program. The description must include at least the coverage required by § 123.404 and § 123.405 of this subpart. Whenever the scope of coverage is revised, the State Agency shall disseminate and publish a revised description of it.

§ 123.405 Health maintenance organizations (HMOs).

(a) *Required coverage.* With respect to an HMO or a health care facility controlled, directly or indirectly, by an HMO or combination of HMOs, the State Agency shall review any activity specified in § 123.404 which is undertaken by or on behalf of an inpatient health care facility (unless these activities are exempt under paragraph (b)(1) of this section). In addition, the State Agency shall review the acquisition of major medical equipment by an ambulatory care facility of an HMO to the extent required by § 123.404(a)(4) and § 123.404(d)(2) (unless the acquisition is exempt under paragraph (b)(1) of this section). A State program may not exceed the coverage specified in this paragraph.

EXPLANATORY NOTE: A list of examples illustrating this coverage follows: (1) Major medical equipment acquired by HMOs which is not owned by or located in a health care facility and which is used primarily for inpatients of a hospital must be reviewed (unless the project is exempt); further, major medical equipment acquired by an HMO and located in a health care facility must be reviewed (unless the project is exempt). (2) A capital expenditure for an ambulatory clinic proposed by an HMO which expenditure is not proposed by or on behalf of an inpatient health care facility is not subject to review. (3) The establishment of an HMO is not subject to certificate of need review. (4) Any capital expenditure exceeding the expenditure minimum by or on behalf of an HMO's inpatient health care facility must be reviewed (unless the project is exempt). (5) A capital expenditure for the addition of ten beds to an HMO's hospital must be reviewed (unless the project is exempt).

(b) *Exemptions*—(1) *Exemptions from review.* The State Agency shall exempt from review any activity described in paragraph (a) of this section if the applicant meets the requirements of paragraph (b)(2) of this section and if the activity is proposed to be undertaken by:

(i) An HMO or a combination of HMOs if (A) the HMO or combination of HMOs has, in the service area of the HMO or the service areas of the HMOs in the combination, an enrollment of at least 50,000 individuals, (B) the facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals, and (C) at least 75 percent of the patients who can reasonably be expected to receive the health service will be individuals enrolled with the HMO or HMOs in the combination; or

(ii) A health care facility if (A) the facility primarily provides or will provide inpatient health services, (B) the facility is or will be controlled, directly or indirectly, by an HMO or a combination of HMOs which has, in the service area of the HMO or service areas of the HMOs in the combination, an enrollment of at least 50,000 individuals, (C) the facility is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals, and (D) at least 75 percent of the patients who can reasonably be expected to receive the health service will be individuals enrolled with the HMO or HMOs in the combination; or

(iii) A health care facility (or portion thereof) if (A) the facility is or will be leased by an HMO or combination of HMOs which has, in the service area of the HMO or the service areas of the HMOs in the combination, an enrollment of at least 50,000 individuals and, on the date the application is submitted under paragraph (b)(2) of this section, at least fifteen years remain in the term of the lease, (B) the facility is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals, and (C) at least 75 percent of the patients who can reasonably be expected to receive the health service will be individuals enrolled with the HMO.

(2) *Application for exemption.* (i) An activity of an HMO, combination of HMOs, or health care facility shall not be exempt under paragraph (b)(1) of this section unless—

(A) The applicant has submitted, at the time and in the form and manner prescribed by the State Agency, an application for an exemption to the State Agency and the appropriate health systems agency,

(B) The application contains the information respecting the HMO, combination, or facility and the proposed offering, acquisition, or obligation that the State Agency may require to determine if the HMO or combination meets the requirements of paragraph (b)(1) of this section or the facility meets or will meet those requirements, and

(C) The State Agency approves the application.

(ii) The State Agency shall approve an application submitted under this paragraph if the applicable requirements of paragraph (b)(1) of this section have been met or will be met on the date the proposed activity for which an exemption was requested will be undertaken.

(3) *Sale, lease, acquisition, or use of exempt facilities or equipment.* The State program must provide that a health care facility (or portion thereof) or medical equipment for which an exemption was granted under paragraph (b)(1) of this section may not be sold or leased, a controlling interest in the facility or equipment or in a lease of the facility or equipment may not be acquired, and a health care facility described in paragraph (b)(1)(iii) of this section which was exempted under paragraph (b)(1) of this section may not be used by any person other than the lessee described in paragraph (b)(1)(iii), unless,

(i) The State Agency issues a certificate of need for the sale, lease, acquisition, or use, or

(ii) The State Agency determines, upon application, that (A) the entity which intends to buy or lease the facility or equipment, or acquire the controlling interest in it, or which intends to use it, is an HMO or a combination of HMOs which meets the requirements of paragraph (b)(1)(i)(A) of this section; and (B) with respect to the facility or equipment, the entity meets the requirements of paragraph (b)(1)(i) (B) and (C) of this section or of paragraph (b)(1)(ii) (A) and (B) of this section.

(4) *Method of payment.* The method of payment for services (i.e., prepaid or fee-for-service) is not relevant in determining whether an activity is subject to review under this subpart.

(c) *Inclusion in health plans.* If an HMO or a health care facility which is controlled, directly or indirectly, by an HMO applies for a certificate of need, a State Agency may not disapprove the application solely because the proposal is not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(d) *Required approval.* Notwithstanding general review criteria established in accordance with § 123.412, if an HMO or a health care facility which is controlled, directly or indirectly, by an HMO applies for a certificate of need, the State Agency shall approve the application if it finds (in accordance with § 123.412(a)(13)) that (1) approval of the application is required to meet the needs of the members of the HMO and of the new members which the HMO can reasonably be expected to enroll, and (2) the HMO is unable to provide, through services or facilities which can reasonably be expected to be available to the

HMO, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operations of the HMO and which makes these services available on a long-term basis through physicians and other health professionals associated with it.

(e) *Sale, acquisition, or lease of approved facilities or equipment.* The State program must provide that except as provided in paragraph (b)(2) of this section and notwithstanding § 123.406, a health care facility (or portion thereof) or medical equipment for which a certificate of need was issued under this section may not be sold or leased, and a controlling interest in the facility or equipment or in a lease of the facility or equipment may not be acquired, unless the State Agency issues a certificate of need for the sale, acquisition, or lease.

§ 123.406 Notice of intent.

The State program must provide as follows: (a) *Major medical equipment.* At least 30 days before any person enters into a contract to acquire major medical equipment which will not be owned by or located in a health care facility, the person shall notify the State Agency of the State in which the equipment will be located and the appropriate health systems agency of the person's intent to acquire the equipment and of the use that will be made of the equipment (see § 123.404(a)(4)(ii)). The notice must be in writing and contain all information the State Agency requires in accordance with § 123.410(a)(4).

(b) *Acquisition of health care facilities.* At least 30 days before any person acquires or enters into a contract to acquire an existing health care facility, the person shall notify the State Agency of the State in which the facility is located and the appropriate health systems agency of the person's intent to acquire the facility and of the services to be offered in the facility and its bed capacity (see § 123.404(a)(5)). The notice must be made in writing and must contain all information the State Agency requires in accordance with § 123.410(a)(4).

(c) *Construction projects.* The State Agency shall have procedures for persons proposing construction projects to submit to the State Agency and the appropriate health systems agency, as early as possible in the course of planning the project, a notice of intent in as much detail as may be necessary to inform the agencies of the scope and the nature of the project.

§ 123.407 Required approvals.

(a) Except as provided in paragraph (b) of this section, the State Agency shall issue a certificate of need for a proposed capital expenditure if (1) the capital expenditure is required (i) to eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or (ii) to comply with State licensure standards, or (iii) to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under Title XIX of that Act, and (2) the State Agency has determined that (i) the facility or service for which the capital expenditure is proposed is needed, and (ii) the obligation of the capital expenditure is consistent with the State health plan.

EXPLANATORY NOTE: For applications which meet the requirements of § 123.407(a), the State Agency shall use procedures and apply criteria (to the extent they are appropriate to determine need) as required by this subpart. If the State Agency determines that the facility or service for which the expenditure is proposed is not needed (and thus that the expenditure to correct the deficiency is not needed), it must deny the certificate of need as required by § 123.408(a). If the State Agency determines that the expenditure is not consistent with the State health plan, it must deny the certificate of need unless there is an emergency that poses an imminent threat to public health (see § 123.403(d)). Even in such a case, there is no requirement that the State Agency issue a certificate of need. The State Agency should consider alternative means of dealing with the threat to public health. State Agencies may wish to expedite the review of applications intended to correct deficiencies which pose a threat to the public health. In so doing, State Agencies may use any exceptions to the required review procedures which have been approved under § 123.411.

(b) Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with certain licensure, certification, or accreditation standards are subject to review using the criteria developed under § 123.412.

§ 123.408 Enforcement.

(a) The State certificate of need program must provide that (1) State Agencies may only issue a certificate of need for those obligations of capital expenditures, offerings of institutional health services, and acquisitions of major medical equipment which are found to be needed; and (2) persons may only obligate capital expenditures, offer institutional health services or acquire major medical equipment after a certificate of need is issued or an exemption under § 123.405(b) is obtained; and (3) persons may not obligate capital expenditures, offer institutional health services, or acquire major medical equipment if a certificate of need authorizing that obligation, offering, or acquisition has been withdrawn by the State Agency.

(b) The State certificate of need program must provide sanctions, such as the denial or revocation of a license to operate, civil or criminal penalties, or injunctive relief, which the Secretary finds sufficient to ensure compliance with paragraph (a) of this section.

§ 123.409 Adoption and public notice of review procedures and criteria.

(a) Each State Agency shall adopt, and review and revise as necessary, review procedures and criteria in accordance with the requirements of this subpart prior to conducting reviews.

(b) The State Agency, the Statewide Health Coordinating Council, and the health systems agencies within the State shall cooperate in the development of procedures and criteria under this subpart to the extent appropriate to achieve efficient reviews and consistent criteria for reviews.

(c) Before adopting the review procedures and criteria required by this subpart or any revisions of the procedures and criteria, the State Agency shall give interested persons an opportunity to offer written comments on the procedures and criteria, or any revisions thereof, which it proposes to adopt.

(1) The State Agency shall distribute copies of its proposed review procedures and criteria, and proposed revisions thereof, to Statewide health agencies and organizations, the Statewide Health Coordinating Council, each health systems agency for a health service area located in the State, and any agency which establishes rates for health care facilities or HMOs in the State.

(2) The State Agency shall publish, in one or more newspapers of general circulation in the State, a notice stating that review procedures and criteria, or revisions thereof, have been proposed for adoption and are available at specified addresses for inspection and copying.

(3) A State Agency may request from the Secretary an exception to the requirement of paragraph (c)(2) of this section. The request must be in writing and must contain a detailed explanation of the reasons for the request and of the substitute publication procedures that the agency intends to follow if the exception is approved. The Secretary may grant an exception if the Secretary determines that the proposed substitute procedures do not adversely and substantially affect the rights of affected persons.

(d) Each State Agency shall distribute copies of its adopted review procedures and criteria, and any revisions thereof, to the agencies and organizations specified in paragraph (c)(1) of this section and to the Secretary, and shall provide copies to other persons upon request.

§ 123.410 Procedures for State Agency review.

(a) The procedures adopted and used by a State Agency for conducting the reviews covered by this subpart must include at least the following:

(1) *Schedules for submitting applications.* Establishment of a schedule for submission of applications to the State Agency. The schedule must provide for the review of all completed applications pertaining to similar types of services, facilities, or equipment af-

fecting the same health service area to be considered in relation to each other ("batched") at least twice a year.

(i) Applications which satisfy the requirements of § 123.407(a) for required approval are not required to be batched.

(ii) With respect to health services, the State Agency shall, unless the State establishes other categories satisfactory to the Secretary, batch applications at least according to the following categories: general medical-surgical, psychiatric, obstetric, pediatric, skilled nursing, and intermediate care. State Agencies may subdivide these categories and may establish additional categories.

(2) *Notification of the beginning of a review.* Timely written notification to affected persons of the beginning of a review, and, if a person has asked the State Agency to place the person's name on a mailing list maintained by the State Agency, notification to the person. Notification must include the proposed schedule for the review, the period within which a public hearing during the course of the review may be requested by affected persons, and the manner in which notification will be provided of the time and place of any hearing so requested.

(i) For purposes of this paragraph, the date of notification is the date on which the notice is sent or the date on which the notice appears in a newspaper of general circulation, whichever is later.

(ii) Written notification to members of the public and third party payers may be provided through newspapers of general circulation in the health service area and public information channels; notification to all other affected persons must be by mail (which may be as part of a newsletter).

(3) *Review period.* Schedules which provide for starting reviews in a timely fashion and which establish the period within which the State Agency will approve or disapprove applications for certificates of need and for exemptions under § 123.405(b).

(i) If, after a review has begun, the State Agency or the health systems agency requires the applicant to submit additional information, that agency shall give the applicant at least fifteen days to submit the information, and upon request of the applicant, the State Agency shall extend its review period at least fifteen days. This extension must apply to all other applications which have been batched with the application for which additional information is required.

(ii) The schedule must provide that no certificate of need review shall, to the extent practicable, take longer than 90 days from the date that notification is sent to all affected persons under paragraph (a)(2) of this section to the date of the written findings made under paragraph (a)(6) of this section. The State Agency shall adopt criteria acceptable to the Secretary for determining when it would not be practicable to complete a review within 90 days.

(iii) The schedule must set forth the period within which the appropriate health systems agency shall complete its review under § 122.308(a)(3) of this title, and provide its recommendation with respect to the project to the State Agency. However, the period allotted by the State Agency to the health systems agency for completion of its review and submission of its recommendation may not be less than 60 days, except with the written consent of the health systems agency.

(4) *Information requirements.* Provision for persons subject to a review to submit to the State Agency, in the form and manner and containing the information which the State Agency shall prescribe and publish, any information that the State Agency may require concerning the subject of the review.

(i) The information requirements may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed.

(ii) The State Agency may require no information of a person subject to review which is not prescribed and published as being required.

(iii) The State Agency shall develop procedures to ensure that requests for information in connection with a review under this subpart are limited to only that information which is necessary for the State Agency to perform the review.

(5) *Periodic reports.* Submission of periodic reports by providers of health services and other persons subject to review respecting the development of proposals subject to review.

(6) *Written findings and conditions.* Provision for written findings (including, as appropriate, the required findings under § 123.405(d) and § 123.413(a)) which state the basis for any final decision made by the State Agency. When a certificate of need is to be issued, these findings must include the finding of need required by § 123.408(a)(1). The State Agency may not make its final decision subject to any condition unless the condition directly relates to criteria established under § 123.412 or criteria prescribed by regulation by the State Agency in accordance with an authorization under State law. The State Agency shall send written findings to the applicant and to the health systems agency for the health service area in which the project is proposed, and shall make them available to others upon request. In the case of a project proposed by an HMO, the State Agency shall also send these written findings to the appropriate regional office of the Department of Health and Human Services at the time these are sent to the applicant.

(7) *Notification of the status of a review.* Timely notification, upon request, of providers of health services and other persons subject to review under this subpart of the status of the State Agency review, findings made in the course of the review, and other appropriate information respecting the review.

(8) *Public hearing in the course of review.* Provision for a public hearing in the course of agency review (and before the State Agency makes its decision) if requested by any affected person.

(i) The State Agency shall provide at least 30 days from the date of written notification of the beginning of a review (see paragraph (a)(2) of this section) within which a public hearing during the course of the review may be requested. The State Agency shall, prior to the hearing, provide notice of the hearing, in accordance with its procedure adopted under paragraph (a)(2) of this section.

(ii) In a hearing, any person shall have the right to be represented by counsel and to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing. Any person affected by the matter may conduct reasonable questioning of persons who make relevant factual allegations.

(iii) The agency shall maintain a verbatim record of the hearing.

(iv) The agency may not impose fees for the hearing.

(v) Paragraph (c) of this section provides that the requirement for a public hearing in the course of review is satisfied if the State Agency delegates the hearing responsibility to the appropriate health systems agency and the health systems agency follows the procedures required by this subsection. In the event that a person qualifying under the State Agency definition of "affected person" is not provided an opportunity for a public hearing by the health systems agency, due to a difference in that agency's definition of "affected persons," the State Agency must provide that person an opportunity for a public hearing.

(9) *Ex parte contacts.* Provision that, after the commencement of a hearing under paragraphs (a)(8) and (a)(11) of this section and before a decision is made, there shall be no ex parte contacts between (i) any person acting on behalf of the applicant or holder of a certificate of need, or any person opposed to the issuance or in favor of withdrawal of a certificate of need and (ii) any person in the State Agency who exercises any responsibility respecting the application or withdrawal.

(10) *Statement of reasons.* Provision that if the State Agency makes a decision which is inconsistent with a recommendation made by the health systems agency, the goals of the applicable health systems plan, or the priorities of the applicable annual implementation plan, the State Agency shall submit to the health systems agency and to the applicant a written, detailed statement of the reasons for the inconsistency.

(11) *Public hearings for reconsideration of a State Agency decision.* Provision that any person may, for good cause shown, request in writing a public hearing for purposes of reconsideration by the State Agency of its decision.

(i) The agency may not impose fees for the hearing.

(ii) For purposes of this paragraph, a request for a public hearing shows good cause if it (A) presents significant relevant information not previously considered by the State Agency which, with reasonable diligence, could not have been presented before the State Agency made its decision, (B) demonstrates that there have been significant changes in factors or circumstances relied upon by the State Agency in reaching its decision, (C) demonstrates that the State Agency has materially failed to follow its adopted procedures in reaching its decision, or (D) provides any other basis which the State Agency determines constitutes good cause.

(iii) To be effective, a request for a hearing must be received within 30 days of the State Agency decision, and the hearing must commence within 30 days of receipt of the request, except that where any different time periods for these procedures are established under State law, the latter shall govern.

(iv) The State Agency shall send notification of the public hearing, prior to the date of the hearing, to the person requesting the hearing, the person proposing the project and the health systems agency for the health service area in which the project is proposed, and to others upon request.

(v) The State Agency shall make written findings which state the basis for its decision within 45 days after the conclusion of the hearing, except that where any different time period is established under State law, the latter shall govern.

(vi) A decision of the State Agency following a public hearing under this subparagraph shall be considered a decision of the State Agency for purposes of paragraphs (a)(6), (7), (10), (13), (14), and (15) of this section.

NOTE: Nothing in these regulations requires that a person must request a public hearing for reconsideration of a State Agency decision before obtaining administrative review (see paragraph (a)(13) of this section) or judicial review (see paragraph (a)(14) of this section). However, it is possible that applicable State law imposes such a requirement.

(12) *Maximums on capital expenditures.* Provision that, in issuing a certificate of need, the State Agency shall specify the maximum capital expenditure which may be obligated under the certificate. The State Agency shall (i) prescribe the method used to determine capital expenditure maximums, (ii) establish procedures to monitor capital expenditures obligated under certificates, and (iii) establish procedures to review projects for which the capital expenditure maximum is exceeded or expected to be exceeded.

(13) *Administrative review.* Provision that upon request of any affected person, the decision of the State Agency to issue, deny, or withdraw a certificate of need or to grant or deny an exemption shall be administratively reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, or, if there is no such State law, by an entity (other than the State Agency) designated by the Governor.

(i) To be effective, the request must be received within 30 days of the State Agency decision, and the review must commence within 30 days of receipt of the request, except that where any different time periods for these procedures are established under State law governing the practices and procedures of administrative agencies, the latter shall govern.

(ii) The decision of the reviewing agency must be made in writing within 45 days after the conclusion of the review, except that where any different time period is required under State law governing the practices and procedures of administrative agencies, the latter shall govern. The State Agency shall send these written findings to the person proposing the project, the person requesting the review, the appropriate health systems agency, and to others upon request.

(iii) The decision of the reviewing agency shall be considered the final decision of the State Agency. However, if permitted by applicable State law, the reviewing agency may remand the matter to the State Agency for further action or consideration.

NOTE: Nothing in these regulations requires that a person must request administrative review before obtaining judicial review (see paragraph (a)(14) of this section). However, it is possible that applicable State law imposes such a requirement.

(14) *Judicial review.* Provision that any person adversely affected by a final decision of a State Agency with respect to a certificate of need or an application for an exemption may, within a reasonable period of time after the decision is made (and any administrative review of it completed), obtain judicial review of it in an appropriate State court.

(i) The State court shall affirm the decision of the State Agency unless it finds it to be arbitrary or capricious or not made in compliance with applicable law.

(ii) For purposes of this paragraph, "person adversely affected" shall include the State Agency, any person who meets the definition of "affected person" in § 123.401, and any person who participated in the proceeding before the State Agency.

(15) *Annual reports of the State Agency.* Preparation and publication, at least annually, of reports by the State Agency of the reviews being conducted (including a statement concerning the status of each review) and of the reviews completed by the agency since the publication of the last report and a general statement of the findings and decisions made in the course of those reviews.

(16) *Public access.* Access by the general public to all applications reviewed by the State Agency and to all other written materials essential to any State Agency review.

(17) *Failure to act on an application within the required time.* Provision that if the State Agency fails to approve or disapprove an application for a certificate of need or an exemption under § 123.405(b) within the applicable period, the applicant may, within a reasonable period of time following the expiration of that period, bring an action in an appropriate State court to require the State Agency to approve or disapprove the application. A certificate of need or an exemption may not be issued or denied solely because the State Agency failed to reach a decision.

(18) *Withdrawal of a certificate of need.* Provision that an application for a certificate of need shall specify the time the applicant will require to make the service or equipment available or to complete the project and a timetable for making the service or equipment available or to complete the project. After the issuance of a certificate of need, the State Agency shall periodically review the progress of the holder of the certificate in meeting the timetable specified in the approved application. If on the basis of this review the State Agency determines that the holder of a certificate is not meeting the timetable and is not making a good faith effort to meet it, the State Agency may, after considering any recommendation made by the appropriate health systems agency, withdraw the certificate. In withdrawing a certificate of need, the State Agency shall follow the procedures at paragraph (a)(2), (6), (7), (8), (9), (10), (11), (13), (14), and (15) of this section.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed.

(c) The procedures may provide that the requirements of paragraph (a) (4) or (5) of this section shall be considered satisfied if the appropriate health systems agency has provided for the corresponding procedure found at § 122.308(a) (4) or (5) of this title. The procedures of paragraph (a)(8) of this section shall be considered satisfied if the State Agency delegates the hearing responsibility to the appropriate health systems agency and the health systems agency follows the procedures at paragraph (a)(8) of this section.

§ 123.411 Exceptions to use of procedures.

(a) The Secretary may approve an exception to any of the required review procedures under § 123.410 either in response to a written request from a State Agency or as a general exception of which any State Agency may avail itself. In approving a general exception, the Secretary will establish substitute procedures where appropriate.

(b) Before availing itself of a general exception approved by the Secretary, the State Agency shall follow the notice and comment procedures of § 123.409(c). Before submitting a written request for an exception under this section, the State Agency shall follow the notice and comment procedures of § 123.409(c) and shall submit to the Secretary with its request copies of all comments which it receives. Before approving the request, the Secretary will (1) review copies of the comments submitted by the State Agency and (2) determine that the procedures which will be used are consistent with the purposes of the Act and will not adversely and substantially affect the rights of affected persons.

(c) The State Agency shall, in accordance with the requirements of § 123.409(d), distribute a notice of the approved exceptions and of any substitute procedures established under this section.

§ 123.412 Criteria for State Agency review.

(a) The State Agency shall adopt, and use as applicable, specific criteria for conducting the reviews covered by this subpart. The criteria must be based only on the following general considerations, except that the State Agency may include any additional criteria which it prescribes by regulation in accordance with an authorization under State law. In the case of an HMO or an ambulatory care facility or health care facility controlled, directly or indirectly, by an HMO or combination of HMOs, the criteria must be based only on the considerations set forth in paragraph (a)(13) of this section.

(1) The relationship of the health services being reviewed to the applicable health systems plan, annual implementation plan, and State health plan.

(2) The relationship of services reviewed to the long-range development plan (if any) of the person providing or proposing the services.

(3) The availability of less costly or more effective alternative methods of providing the services to be offered, expanded, reduced, relocated, or eliminated.

(4) The immediate and long-term financial feasibility of the proposal, as well as the probable effect of the proposal on the costs of and charges for providing health services by the person proposing the service.

(5)(i) The need that the population served or to be served has for the services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, are likely to have access to those services.

(ii) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, and the elderly, to obtain needed health care.

(6) The contribution of the proposed service in meeting the health related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low income persons, racial and ethnic minorities, women, and handicapped persons), particularly those needs identified in the applicable health systems plan, annual implementation plan, and State health plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the State Agency shall consider:

(i) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(ii) The performance of the applicant in meeting its obligation, if any, under any applicable Federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant);

(iii) The extent to which Medicare, Medicaid and medically indigent patients are served by the applicant; and

(iv) The extent to which the applicant offers a range of means by which a person will have access to its services (e.g., outpatient services, admission by house staff, admission by personal physician).

NOTE: Where appropriate, the State Agency may also consider other access issues, such as: (1) the extent to which the applicant grants medical staff privileges to physicians who serve the medically underserved; and (2) the extent to which the applicant takes action necessary to remove barriers that limit access to the health services of the applicant. These barriers may include unavailability of public transportation; absence of translation services where a substantial portion of the population of the health service area does not speak English as its primary language; building designs that substantially hinder use of the facility; and financial barriers (e.g., pre-admission deposits).

(7) The relationship of the services proposed to be provided to the existing health care system of the area in which the services are proposed to be provided.

(8) The availability of resources (including health personnel, management personnel, and funds for capital and operating needs) for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the applicable health systems plan, annual implementation plan or State health plan.

(9) The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services.

(10) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

(11) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes.

(12) Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.

(13) The special needs and circumstances of HMOs. These needs and circumstances shall be limited to:

(i) The needs of enrolled members and reasonably anticipated new members of the HMO for the health services proposed to be provided by the organization; and

(ii) The availability of the new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the agency shall consider only whether the services from these providers:

(A) Would be available under a contract of at least five years duration;

(B) Would be available and conveniently accessible through physicians and other health professionals associated with the HMO. (For example—whether physicians associated with the HMO have or will have full staff privileges at a non-HMO hospital);

(C) Would cost no more than if the services were provided by the HMO; and

(D) Would be available in a manner which is administratively feasible to the HMO.

(14) The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which

local conditions offer special advantages.

(15) In the case of a construction project:

(i) The costs and methods of the proposed construction, including the costs and methods of energy provision, and

(ii) The probable impact of the construction project reviewed on the costs of providing health services by the person proposing the construction project and on the costs and charges to the public of providing health services by other persons.

(16) The special circumstances of health care facilities with respect to the need for conserving energy.

(17) In accordance with section 1502(b) of the Act, the factors which affect the effect of competition on the supply of the health services being reviewed.

(18) Improvements or innovations in the financing and delivery of health services which foster competition, in accordance with section 1502(b) of the Act, and serve to promote quality assurance and cost effectiveness.

(19) In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed.

(20) In the case of existing services or facilities, the quality of care provided by those facilities in the past.

(21) When an application is made by an osteopathic or allopathic facility for a certificate of need to construct, expand, or modernize a health care facility, acquire major medical equipment, or add services, the need for that construction, expansion, modernization, acquisition of equipment, or addition of services shall be considered on the basis of the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients. The State Agency shall consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

EXPLANATORY NOTE: This provision seeks to ensure that the need for and availability of services and facilities for osteopathic physicians and patients will be considered.

(b) State Agencies shall apply all applicable criteria based on the considerations listed at § 123.412. Criteria adopted for reviews in accordance with paragraph (a) of this section may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.

§ 123.413 Required findings on access.

(a) Under § 123.412(a) (5) and (6), the State Agency is required to develop criteria based on considerations relating to the need of the population to be served for the proposed project and the extent to which the residents of the area will have access to the project. For each project it approves, the State Agency shall make a written finding (which shall take into account the current accessibility of the facility as a whole) on the extent to which the project will meet the State Agency's criteria developed based on the considerations in § 123.412(a) (5) and (6), except in the following cases:

(1) Where the project is one described in § 123.407(a) (projects to eliminate or prevent certain imminent safety hazards or to comply with certain licensure or accreditation standards); or

(2) Where the project is a proposed capital expenditure not directly related to the provision of health services or to beds or major medical equipment; or

(3) Where the project is proposed by or on behalf of an HMO or a health care facility which is controlled, directly or indirectly, by an HMO.

EXPLANATORY NOTE: When a project is approved, then in addition to the written findings required by § 123.410(a)(6), to the extent that a project does not fall within one of these exceptions, a written finding under § 123.413 regarding the criteria on need and access developed under § 123.412(a) (5) and (6) is required. Examples of when the written finding is required as to whether a project satisfies the State Agency's criteria for need and access are as follows: (1) The applicant proposes to make a capital expenditure of $400,000 required solely to comply with State licensure standards. The written finding is not required. (2) The applicant proposes to provide a new coronary care service with annual operating costs of more than the expenditure minimum. The written finding is required if the project is approved. (3) The applicant proposes to make a capital expenditure of $200,000 to repave its parking lot, or to acquire computerized data processing equipment, or to repair or upgrade its heating or air conditioning equipment. The written finding is not required. (4) The applicant proposes to make a capital expenditure to add fifteen beds to its obstetrical ward. The written finding is required if the project is approved. (5) The applicant proposes to make a capital expenditure to renovate the pediatric ward of its facility. If the project is approved, a written finding is required because the project is directly related to the provision of health services.

(b) In any case where the State Agency finds that an approved project does not satisfy the State Agency's criteria based on the considerations in § 123.412(a) (5) or (6), it may, if it approves the application, impose the condition that the applicant take affirmative steps to meet those criteria.

(c) When this written finding is required, the State Agency, in evaluating the accessibility of the project, must take into account the current accessibility of the facility as a whole. If the State Agency disapproves a project for failure to meet the need and access criteria, it must so state in its written findings under § 123.410(a)(6).

(d) In any case where the State Agency finds that a project does not satisfy the State Agency's criteria based on the considerations in § 123.412(a) (5) or (6), it shall so notify in writing the applicant and the appropriate Regional Office of the Department of Health and Human Services.

Subpart F—Special Provisions for States—Section 1536 of the Act

§ 123.501 Additional grants to certain State agencies

In addition to grants pursuant to section 1525 of the Act, a State Agency designated for the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, American Samoa, the Northern Mariana Islands, or any other State determined by the Secretary to meet the requirements of section 1536(a) of the Act may, where the State Agency agrees to meet the requirements of § 123.502, receive a grant under section 1516 of the Act and this subpart.

(a) *Application.* An application for a grant under this section must conform to the requirements of 42 CFR 122.203 and in addition shall include a detailed description of the functions under section 1513 of the Act which the applicant will perform during the period of the designation agreement, and the manner in which the State Agency proposes to carry out such functions.

(b) *Amount of the grant.* (1) Where a State Agency has entered into a Conditional Designation Agreement under § 123.105, the amount of the grant to the State Agency will be computed in accordance with 42 CFR 122.204(b) as if the State Agency were a conditionally designated health systems agency.

(2) Where a State Agency has entered into a Full Designation Agreement under § 123.106, the amount of the grant to the State Agency will be computed in accordance with 42 CFR 122.204(b) as if the State Agency were a fully designated health systems agency.

(c) *Population.* For purposes of determining the amount of the grant under this section, the population of a State will be determined by the Secretary in accordance with 42 CFR 122.205.

(d) *Assurance of expenditure of non-Federal funds.* A State Agency which qualifies for a grant under this section may receive an increased amount of grant funds in accordance with section 1516 of the Act and 42 CFR 122.204 where the State Agency provides assurance in accordance with 42 CFR 122.206 that it will expend or obligate non-Federal funds during the grant period for the purposes for which grants under this section may be made.

(e) *Grant payments.* Payments to a grantee of a grant award will be made in accordance with 42 CFR 122.207.

(f) *Use of grant funds.* Funds granted pursuant to this section, as well as other funds required as a condition of the grant to be used in performance of the approved activity, shall be expended in accordance with section 1516 of the Act, terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74. Such funds shall be available for obligation only during the period of the State Agency's designation agreement current at the time of the grant award.

(g) *Nondiscrimination.* The provisions of 42 CFR 122.209 shall apply to grants made under this section.

(h) *Grantee accountability.* The provisions of paragraphs (a) and (b) of 42 CFR 122.211 shall apply to grants made under this section.

(i) *Applicability of 45 CFR Part 74.* The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants made under this section.

(j) *Additional conditions.* The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

§ 123.502 Additional requirements for State agencies.

In addition to the other provisions of this Part, the provisions of this section shall apply to a State Agency which receives a grant under section 1516.

(a) *Additional functions*—(1) *Conditional designation.* In the case of a State Agency designated pursuant to a Conditional Designation Agreement, the State Agency shall perform such of the functions prescribed by section 1513 of the Act and 42 CFR 122.107(c) as the secretary, in writing, directs it to perform in accordance with 42 CFR 122.106 (b) and (c), as though the State were a health service area and the State Agency a health systems agency for such area.

(2) *Full designation agreement.* In the case of a State Agency designated pursuant to a Full Designation Agreement, the State Agency shall perform the functions prescribed by section 1513 of the Act and 42 CFR 122.107(c), as though the State were a health service area and the State Agency a health systems agency for such area. *Provided,* That: The requirements of section 1513(b)(2) of the Act and 42 CFR 122.107(c)(2) (relating to the development of a health systems plan); section 1513(f) of the Act and 42 CFR 122.107(c)(14) (relating to the review of new institutional health services proposed to be offered or developed); section 1513(g) of the Act and 42 CFR 122.107(c)(15) (relating to periodic review of all institutional health services); and section 1513(h) of the Act and 42 CFR 122.107(c)(16) (relating to recommendation of projects for modernization, construction and conversion of medical facilities) shall not apply for purposes of this section.

(b) *Review and comment by SHCC.* The State Agency shall afford the SHCC for such State a reasonable opportunity to review and comment upon the following actions by the State Agency before such actions are made final:

(1) The establishment, annual review, and amendment of the annual implementation plan ("AIP") as described in 42 CFR 122.107(c)(3);

(2) The development and publication of specific plans and programs for achieving the objectives established in the AIP, as described in 42 CFR 122.107(c)(6);

(3) The making of grants and contracts from the Area Health Services Development Fund pursuant to section 1640 of the Act, as described in 42 CFR 122.107(c)(9);

(4) The approval or disapproval of each proposed use of Federal funds within the State, as described in 42 CFR 122.107(c)(17).

(c) *State agency staff.* Notwithstanding any other provisions of this Part relating to State Agency staff, a State Agency to which this section is applicable shall have a staff which meets the requirements of 42 CFR 122.110. The Secretary may, for good cause shown upon application by any such State Agency, waive the requirements of 42 CFR 112.110 in whole or in part with respect to such agency. The requirements of section 1522(b)(4)(B) of the Act and § 123.104(b)(6) (relating to personnel standards on a merit basis) shall apply to each State Agency under this section.

§ 123.503 Special provisions for membership for Statewide Health Coordinating Councils.

The membership of the SHCC shall number not less than 16 and shall be appointed by the Governor of such State in accordance with the provisions of 42 CFR 122.109(b), relating to the composition of the governing body of a health systems agency; *Provided*, That: In the case of the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, American Samoa, or the Northern Mariana Islands any of the requirements of 42 CFR 122.109(b) may be waived by the Secretary upon the written request of the Governor supported by evidence sufficient to satisfy the Secretary that such requirement cannot be met or would, under the circumstances, be inconsistent with the purposes of the Act.

§ 123.504 Preliminary State health plan.

(a) In the case of a State Agency designated for the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, the Northern Mariana Islands and any other State determined to meet the requirements of section 1536 of the Act, the preliminary State health plan shall be established after appropriate consideration of the recommended National Guidelines for health planning policy issued by the Secretary under section 1501, and the priorities set forth in section 1502, and shall be a detailed statement of goals

(1) Describing a healthful environment and health system in the area which, when developed, will assert that quality health services will be available and accessible in a manner which assures continuity of care, at reasonable cost, for all residents of the area;

(2) Which are responsive to the unique needs and resources of the area; and

(3) Which take into account and are consistent with the National Guidelines for health planning policy issued by the Secretary under section 1501 of the Act respecting supply, distribution and organization of health resources.

(b) For purposes of this part, the preliminary State health plan prepared pursuant to this section shall be deemed to be the health systems plan for the State.

Subpart G—State Agency Reviews of Existing Institutional Health Services for Appropriateness

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); secs. 1523 and 1532 of the Public Health Service Act, as amended, 93 Stat. 592-630 (42 U.S.C. 300m-2, 300n-1).

SOURCE: 44 FR 71771, Dec. 11, 1979, unless otherwise noted.

§ 123.601 Definitions.

Except for the term "institutional health services," terms used in this subpart shall have the meaing given them in Subparts A (definitions) and E (certificate of need and review of new institutional health services) of this part. In addition, as used in this subpart:

The term "institutional health services," means health services which (a) are provided through private or public hospitals, rehabilitation facilities, and nursing homes, and (b) entail annual operating costs of at least the expenditure minimum. For purposes of this paragraph, the term "expenditure minimum" means $75,000 for the twelve-month period beginning with October 1979, and for each twelve-month period thereafter, $75,000 or, at the discretion of the State, the figure in effect for the preceding twelve-month period, adjusted to reflect the change in the preceding twelve month period in an index to be specified by the Secretary.

The term "existing institutional health services" or "services" means institutional health services:

(a) Being offered in the State at the time of review for appropriateness, or

(b) Offered at any time in the 12 months prior to the review and also planned to be offered at any time in the 12 months following the review, or

(c) Which will be offered during the 12 months following the review.

A finding of "appropriateness" means a finding that the service meets the needs of a population in accordance with the criteria developed and published under § 123.607.

The term "areawide review" means the review of a specific institutional health service as delivered by all the institutions providing the service in a health service area or State (a) which shall culminate in findings regarding the appropriateness of that service over the entire health service area or State, and (b) which may result in recommendations regarding the appropriateness of that service in a particular institution.

§ 123.602 Purpose and applicability.

Section 1523(a)(6) of the Act requires each State health planning and development agency to review on a periodic basis (but not less often than every 5 years) all institutional health services being offered in the State (hereinafter referred to as an appropriateness review) and, after consideration of the recommendations submitted by health systems agencies under Section 1513(g) of the Act and 42 CFR Part 122, Subpart F, to make public its findings as to the appropriateness of such services. Section 1523(b)(3) of the Act requires the State Agency to complete its findings as to the appropriateness of any existing institutional health service within one year after the date a health systems agency has made its recommendation with respect to the appropriateness of the service under Section 1513(g) of the Act and 42 CFR Part 122, Subpart F. Section 1532(a) of the Act requires that in performing its review functions under Section 1523 of the Act (which includes reviews conducted under Section 1523(a)(6)), each State Agency shall (except to the extent approved by the Secretary) follow procedures and apply criteria developed and published by the State Agency in accordance with regulations of the Secretary. This subpart sets forth minimum procedures and criteria to be used by State Agencies in conducting these reviews; requirements respecting the assumption, conduct, and timing of the appropriateness review function; requirements respecting the coordination with health systems agencies and statewide health coordinating councils and the administrative steps which are necessary for the effective performance of appropriateness reviews.

§ 123.603 Appropriateness review work program.

(a) Each appropriateness review shall be performed on an areawide basis and shall result in a finding as to the appropriateness of the service being reviewed as it is delivered in the State or health service area. The State Agency, may, at the same time, make findings as to the appropriateness of that service in particular institutions.

(b) Each State Agency must, within three months after the effective date of these regulations, develop and submit to the Secretary a work program for the orderly assumption and/or continued performance of appropriateness reviews. This work program will be used in the Secretary's determination of the State Agency's capability of assuming and performing the appropriateness review function in a satisfactory manner as required by Sections 1521(b)(1)(B), (b)(2)(A), and (b)(4) of the Act. The State Agency must submit to the Secretary, with the work program, evidence that prior to its adoption, the public was afforded an opportunity to comment in writing or at a public hearing. It shall also submit a summary of the comments received. The work program shall provide for:

(1) The development of the review procedures and criteria to be applied by the State Agency in the performance of appropriateness reviews, in consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous State(s) where a health service area is shared by more than one State.

(2) The establishment of the definitions of services to be reviewed, priorities among services, and the schedule for reviews of such services, after consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous States where a health service area is shared by both States. In establishment of these definitions, priorities, and schedules, the State Agency must

take into account the statutory time limits applicable to appropriateness reviews by health systems agencies, and the need within the State for priority reviews of the services for which National Guidelines for Health Planning have been issued.

(3) The establishment of requirements for submission by providers of data to be used in performance of appropriateness reviews to the State Agency and to the health systems agencies, after consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous States where a health service area is shared by more than one State. At a minimum, the State Agency shall establish such data requirements for services provided by hospitals and nursing homes during the first and second years, respectively, of its reviews of appropriateness. Data requirements shall be limited to data reasonably needed for appropriateness reviews and the State Agencies shall use existing data sources to the maximum extent feasible.

(4) Plans for initiating appropriateness reviews:

(i) No later than 6 months after the effective date of these regulations if: (A) The State Agency is fully designated prior to the date of publication of these regulations, or (B) the State Agency is conditionally designated and the Secretary has determined that the State Agency is capable of performing appropriateness reviews (see 42 CFR 123.105) prior to the effective date of these regulations; or

(ii) In the case of a State Agency not covered by paragraph (b)(4)(i) of this section, no later than 6 months after: (A) The date of full designation, or (B) the date the Secretary determines that the State Agency, although conditionally designated, is capable of performing appropriateness reviews, whichever is earlier.

(5) Plans for completing areawide reviews of all existing institutional health services within 5 years of the date of the State Agency's initial full designation and during each succeeding 5-year period, but in any event within 1 year of receipt of an appropriate health system agency recommendation. Review schedule priorities may be established, but such review priority setting shall not result in the exclusion from review of any existing institutional health service during any applicable time period.

§ 123.604 Adoption and public notice of review procedures and criteria.

The provisions of 42 CFR 123.406 apply to the adoption and public notice of review procedures and criteria under this subpart.

§ 123.605 Procedures for State Agency review.

(a) The procedures adopted and used by a State Agency for conducting the reviews covered by this subpart shall include at least the following:

(1) Written notification to affected persons of the beginning of a review. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels; notifications to all other affected persons shall be by mail (which may be part of a newsletter). "Affected persons" include at a minimum, the person(s) whose service is being reviewed, the State Agency for each State in which all or any part of the agency's health service area is located, health systems agencies serving contiguous health service areas, health care facilities and HMOs located in the health service area which provide institutional health services, any agency which establishes rates for health care facilities or HMOs in its health service area, and those members of the public who are to be served by the service subject to review.

(2) Schedules for review which provide that no areawide review shall, to the extent practicable, take longer than 180 days from the date of notification to affected persons made in accordance with paragraph (a)(1) of this section to the date of the written findings made in accordance with paragraph (a)(4) of this section.

(3) Provisions for persons subject to a review to submit to the State Agency any information which the State

Agency may require in accordance with its work program under § 123.603(c) concerning the subject of the review in the form and manner and containing the information which the State Agency shall prescribe and publish. These information requirements may vary according to the purpose for which the particular review is being conducted or the type of health service being reviewed; however, the State Agency may require no information of a person subject to review which is not prescribed and published as being required in accordance with § 123.604.

(4) Provision for written findings which state the basis for any findings made by the State Agency.

(5) Notification of providers of health services and other persons subject to the State Agency review of the status of the State Agency's review of the institutional health services, findings made in the course of the review, and other appropriate information respecting the review.

(6) Provision for (i) public hearings in the course of the State Agency review if requested by persons affected by the review; and for (ii) public hearings, for good cause shown, respecting the State Agency finding.

(7) Preparation and publication of regular reports by the State Agency of the reviews being conducted (including a statement concerning the status of each review), and of the reviews completed by the State Agency (including a general statement of the findings made in the course of these reviews) since the publication of the last report.

(8) Access by the general public to all written materials pertinent to any State Agency review.

(9) Provision that if the State Agency makes a finding regarding the appropriateness of an existing institutional health service which is inconsistent with a recommendation made with respect thereto by the health systems agency making such recommendation pursuant to 42 CFR 122.508: (i) the finding (and the record upon which it was made) shall, upon request of the health systems agency, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State health planning and development agency) designated by the Governor, and (ii) the finding of the reviewing agency shall be considered the final finding of the State Agency.

(10) Provision that a decision of the State Agency resulting in an institution-specific finding of inappropriateness shall, upon request of the person(s) providing that service, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State Agency) designated by the Governor. The decision of the reviewing agency shall be considered the final decision of the State Agency.

(11) Provision that if a State Agency (or a reviewing agency, under paragraph (a)(9) of this section) makes a finding regarding an existing institutional health service which the State Agency determines is not consistent with the goals of the applicable health systems plan (established under Section 1513(b)(2) of the Act) or the priorities of the applicable annual implementation plan (established under Section 1513(b)(3) of the Act, the State Agency (or the reviewing agency, as appropriate) shall submit to the appropriate health systems agency a detailed statement of the reasons for the inconsistency.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed.

(c) The procedures adopted for reviews may provide that the requirements of paragraph (a)(3) of this section shall be deemed satisfied for any health service area within the State if the health systems agency has provided for a corresponding procedure.

§ 123.606 Exceptions to use of procedures.

A State Agency may, with respect to any type or group of reviews, request from the Secretary an exception to the requirement that it use review procedures which meet the requirements of § 123.605. The requirements of 42

CFR 123.408 apply to such a request for an exception.

§ 123.607 Criteria for State Agency review.

(a) The State Agency shall adopt, and use as appropriate, specific criteria for conducting the reviews covered by this subpart. These criteria shall relate to availability, accessibility, acceptability, continuity, cost, and quality and shall include at least the general considerations listed below, but in the case of areawide reviews which result in institution-specific findings of services provided by or through HMOs, the considerations shall be limited to those set forth in paragraph (a)(8) of this section.

(1) The relationship of the health services being reviewed to the applicable health systems plans, annual implementation plans, and State health plan.

(2) The relationship of the services reviewed to the long-range development plan (if any) of the person providing the services.

(3) The need that the population served has for the services, and the extent to which low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups have access to those services.

(4) The availability of less costly or more effective alternative methods of providing the services.

(5) The relationship of the services reviewed to the existing health care system of the area in which the services are provided.

(6) The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of the services reviewed and the availability of alternative uses of these resources for the provision of other health services.

(7) The special needs and circumstances of those entities which provide a substantial portion of their services or resources or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health services areas. These entities may include medical and other health professions schools, multidisciplinary clinics, and specialty centers.

(8) The special needs and circumstances of HMOs. In the case of areawide reviews which result in institution-specific findings regarding services provided by or through an HMO, the needs and circumstances shall be limited to:

(i) The needs of enrolled members and reasonably anticipated new members of the HMO for the existing institutional health services provided by the organization.

(ii) Whether the services could be obtained from non-HMO, or other HMO, providers in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

(iii) Any other factors which the State Agency may propose and the Secretary may, in accordance with paragraph (c) of this section, find to be consistent with the purpose of Title XIII of the Act.

(9) The special needs and circumstances of biomedical and behavorial research projects which are designed to meet a national need and for which local conditions offer special advantages.

(10) The contribution of the existing institutional health services in meeting the health related needs of members of medically underserved groups and groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low income persons, racial and ethnic minorities, women, and handicapped persons) particularly those needs identified in the applicable health systems plan and annual implementation plan as deserving of priority.

(11) The special circumstances of health service institutions with respect to the need for conserving energy.

(12) In accordance with Section 1502(b) of the Act, the effect of competition on the supply of the health services being reviewed.

(13) Improvements or innovations in the financing and delivery of health services which foster competition, in accordance with Section 1502(b) of the Act, and serve to promote quality assurance and cost effectiveness.

(14) The quality of care provided by the services or facilities in the past.

(b) Criteria adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed and the purpose of the review. Furthermore, the criteria used in the review of a particular service need not address all six of the characteristics of appropriateness (availability, accessibility, acceptability, continuity, cost, and quality). Should an agency fail to use criteria addressing all six of the characteristics of appropriateness in a review, it must explain this in the finding.

(c) Where a State Agency proposes under paragraph (a)(8)(iii) of this section that it be permitted to base areawide reviews resulting in institution-specific findings of services provided by or through HMOs on criteria which consider factors not set forth in paragraph (a)(8) of this section, it shall do so in a written request to the Secretary, specifying the reasons for the proposal. The Secretary will approve the request if he finds the additional factors to be consistent with the purpose of Title XIII of the Act. Unless the Secretary has approved the additional factors, the State Agency shall base its review solely on the factors set forth in paragraph (a)(8) of this section.

§ 123.608 Required findings.

(a) A State Agency shall, in accordance with the requirements of this subpart, make public its findings with respect to the appropriateness of existing institutional health services.

(b) A State Agency may not make a finding that an existing institutional health service is inappropriate unless it has stated in writing that the service has not met one or more of the established criteria of the State Agency and the ways in which the service failed to meet the criteria, including any that are beyond the control of the person(s) providing that service.

(c) A State Agency, in conducting an areawide review resulting in institution-specific findings, may not make a finding that an existing institutional health service provided by or through an HMO is inappropriate solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same health service area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(d) Where a State Agency has made a finding that a service is inappropriate, the State Agency shall, to the extent practicable, at the same time, make recommendations for remedial action.

PART 124—MEDICAL FACILITY CONSTRUCTION AND MODERNIZATION

Subpart A—Project Grants for Public Medical Facility Construction and Modernization

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APPENDIX—INTERIM PROCEDURES AND CRITERIA FOR REVIEW BY HEALTH SYSTEMS AGENCIES OF APPLICATIONS UNDER SECTION 1625 OF THE PUBLIC HEALTH SERVICE ACT

AUTHORITY: Secs. 215, 1602, 1625, Public Health Service Act (42 U.S.C. 216, 300o-1, 300r), unless otherwise noted.

SOURCE: 42 FR 62270, Dec. 9, 1977, unless otherwise noted.

Subpart A—Project Grants for Public Medical Facility Construction and Modernization

§ 124.1 Applicability.

The regulations of this subpart are applicable to grants under section 1625 of the Public Health Service Act for construction and modernization projects designed to—

(a) Eliminate or prevent imminent safety hazards as defined by Federal, State or local fire, building, or life safety codes or regulations, or

(b) Avoid noncompliance with State or voluntary licensure or accreditation standards.

§ 124.2 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Construction" means construction of new buildings and initial equipment of such buildings and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings. It includes architect's fees, but excludes the cost of off-site improvements and, except with respect to public health centers, the cost of the acquistion of land.

(c) "Cost" means the amount found by the Secretary to be necessary for construction or modernization under a project, except that such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(d) "Equipment" means those items which are necessary for the functioning of the facility but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms, and housekeeping supplies.

(e) "Facility for long-term care" means a facility (including a skilled nursing care or intermediate care facility), providing inpatient care for convalescent or chronic disease patients who require skilled nursing or intermediate care and related medical services—

(1) Which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(2) In which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(f) "Health systems agency" means an agency which has been conditionally or fully designated pursuant to section 1515 of the Act and 42 CFR Part 122.

(g) "Hospital" includes general, tuberculosis, and other types of hospitals, and related facilities such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and education or training facilities for health professional personnel operated as an integral part of a hospital, but does not include any facility furnishing primarily domiciliary care.

(h) "Major repair" means those repairs to an existing building, excluding routine maintenance, which restore the building to a sound state, the cost of which is a least 10 percent of plant value or $200,000, whichever is greater. "Plant value" means the historic book value of the building at the time of application for assistance under this subpart.

(i) "Medical facility" means a hospital, public health center, outpatient medical facility, rehabilitation facility, or a facility for long-term care.

(j) "Modernization" means the alteration, expansion (excluding expansion which increases bed capacity), major repair, remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings, including energy conservation projects.

(k) "Outpatient medical facility" means a facility, located in or apart from a hospital, for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients):

(1) Which is operated in connection with a hospital, or

(2) In which patient care of a specialized nature (such as in an eye clinic, dental clinic, or ambulatory surgical center) is provided under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State, or

(3) Which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full range of diagnostic and treatment services.

(l) "Public health center" means a publicly owned facility for the provision of public health services, including related facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(m) "Quasi-public corporation" means a private, nonprofit corporation which has been formally given one or more governmental powers by a general-purpose unit of government to enable it to carry out its work.

(n) "Rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical evaluation and services, and psychological, social, or vocational evaluation and services, under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of persons licensed to practice medicine or surgery in the State.

(o) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(p) "State" means any one of the several States, the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(q) "State health planning and development agency" or "State Agency" means the agency of a State government which has been conditionally or fully designated under section 1521 of the Act and 42 CFR Part 123.

(r) "Title" means a fee simple, or such other estate or interest in the project site (including a leasehold on which the rental does not exceed 4 percent of the value of the land) as the Secretary finds sufficient to assure undisturbed use and possession for the purpose of construction or modernization and operation of the project for a period of not less than twenty years.

(s) "Urban or rural poverty area" means a census tract, census county division, or minor civil division, as applicable, in which the percentage of the residents with incomes below the poverty level, as defined by the Secretary of Commerce is not less than the percentage derived in accordance with the following sentence. This percentage shall be derived so that the percentage of the total population of the United States residing in all such areas is equal to the percentage of the total population of the United States with incomes below such poverty level, plus five percent.

§ 124.3 Eligibility.

(a) *Eligible applicants.* A grant under section 1625 may only be made to a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation for a project described in paragraph (b) of this section for a medical facility owned, operated, or owned and operated by the State or political subdivision.

(b) *Eligible project.* A grant under section 1625 may be made only for a construction and/or modernization project designed to:

(1) Eliminate or prevent safety hazards which under Federal, State, and/or local fire, building or life safety codes or regulations, will, in the judgment of the Secretary result in one or more of the following:

(i) Loss of licensure for the facility.

(ii) Closing of all or a substantial part of the facility.

(iii) Loss of eligibility for reimbursement under Title XVIII or Title XIX of the Social Security Act; or

(2) Avoid noncompliance with State licensure or voluntary accreditation standards where noncompliance will, in the judgment of the Secretary, result in one or both of the following:

(i) Loss of licensure for the facility.

(ii) Loss of accreditation resulting in loss of eligibility for reimbursement under Title XVIII or Title XIX of the Social Security Act.

§ 124.4 Application.

An application for a grant under this subpart must be submitted directly to the Secretary at such time and in such form and manner as the Secretary may prescribe. The application must be executed by an individual authorized to act for the applicant and assume on behalf of the applicant the obligations imposed by the Act, this subpart, and the terms and conditions of the grant. The application must contain the following:

(a) A description of the site of the project.

(b) A full description, with all appropriate documentation, of:

(1) The imminent safety hazards, licensure and/or accreditation problems of the facility;

(2) The type and amount of assistance sought under this subpart;

(3) The construction of modernization project for which funds are sought, describing how it will remedy the problems described pursuant to paragraph (b)(1) of this section, with a complete schedule for the proposed construction or modernization; and

(4) How failure to remedy the problems described pursuant to paragraph (b) (1) of this section will affect the population served by the facility.

(c) In the case of a modernization project for continuation of existing health services, a finding by the State Agency of the continued need for such services. In the case of a construction or modernization project for new health services, a finding by the State Agency of the need for such services. The finding of need shall be based on the following criteria:

(1) In a State which has a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program, or a program under section 1122 of the Social Security Act, the State Agency shall use the criteria used in conducting reviews under such program. In a State which has more than one such program, the State Agency shall use the criteria of one of the programs and notify the Secretary of the program criteria used.

(2) In a State which does not have a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program or a program under section 1122 of the Social Security Act, the State Agency shall base its finding of need on the following criteria:

(i) Whether the proposed project is needed or projected as necessary to meet the needs in the community in terms of health services required; *Provided,* That projects for highly specialized services (such as open-heart surgery, renal transplantation, or radiation therapy) which will draw from patient populations outside the community in which the project is situated will receive appropriate consideration;

(ii) Whether the proposed project can be adquately staffed and operated when completed;

(iii) Whether the proposed capital expenditure is economically feasible and can be accommodated in the patient charge structure of the health facility without unreasonable increases; and

(iv) Whether the project will foster cost containment or improved quality of care through improved effciency and productivity, including promotion of cost-effective factors such as ambulatory care, preventive health care services, home health care, and design and construction economies, or through increased competition between different health services delivery systems.

(d) Plans and specifications which meet the applicable requirements of 42 CFR 53.101, with the functional program of requirements on which such plans and specifications are based.

(e) An assurance that adequate financial support will be available for completion of the project, supported by a detailed project budget satisfactory to the Secretary which includes all existing and anticipated sources of funds for the project.

(f) An assurance that adequate financial support will be available for maintenance and operation of the project when completed, supported by budgets and detailed expenditure and revenue information satisfactory to the Secretary for both the facility and the applicant for the past three fiscal years and budget and projections of expenditures and revenue for the future three fiscal years. Where a certificate of need or a favorable finding under section 1122 of the Social Security Act is required in order for the project to operate and/or receive reimbursement from governmental programs for health services provided, assurance from the applicant satisfactory to the the Secretary that the applicant will submit, consistent with the provisions of § 124.5(d), any such required certificates of need and/or section 1122 finding.

(g) An assurance that the applicant would not be able to complete the project without the grant applied for, supported by a description of all efforts to obtain funds needed to complete the project and the results of such efforts.

(h) An assurance that all times after the application is approved there will be made available in the facility or portion thereof to be constructed or modernized, a reasonable volume of services to persons unable to pay therefor. The applicant shall comply with the standards and procedures of 42 CFR 53.111, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.111 will be performed by the Secretary, except to the extent they are otherwise assigned.

(i) An assurance that at all times after the application is approved the facility or portion thereof to be constructed or modernized will be made available to all persons residing or employed in the area served by the facility. The applicant shall comply with the standards and procedures of 42 CFR 53.113, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.113 will be performed by the Secretary, except to the extent they are otherwise assigned.

(j) An assurance that title to the project site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project, with such documentation as the Secretary may require.

(k) In the case of an application for construction or modernization of an outpatient medical facility, an assurance, supported by a written transfer agreement (or written documentation that such agreement will be obtained) with identified hospitals, that the services of a general hospital will be available to patients at such facility who are in need of hospital care.

(l) Evidence that:

(1) The appropriate health systems agency has been given the opportunity to review the application in accordance with section 1513(e) of the Act and the requirements of the Appendix

to this subpart, with the result of any such review.

(2) The application has been reviewed in accordance with the applicable requirements of OMB Circular A-95.

(m) An analysis satisfactory to the Secretary and such other information and materials as the Secretary may require concerning the environmental impact of the proposed construction or modernization project.

(n) An assessment satisfactory to the Secretary of the project site in light of the considerations set forth in Executive Order 11296 (31 FR 10663, August 10, 1966) concerning the evaluation of flood hazards in locating Federally supported facilities.

(o) In the case of a project which involves the displacement of persons or businesses, an assurance that the applicant will comply with the applicable provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 et seq.).

(p) (1) An assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a-276a-5, known as the Davis-Bacon Act); and

(2) An assurance that the following conditions and provisions will be included in all construction contracts:

(i) The provisions of "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunity," Form DHHS 514 (rev. July 1976) (issued by the Office of Grants and Procurement Management, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) regulations except in the case of contracts in the amount of $2,000 or less; and pertaining to Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment except in the case of contracts in the amount of $10,000 or less, and

(ii) Representatives of the Secretary will have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(q) Such other information as the Secretary may require.

§ 124.5 Grant evaluation and award.

(a)(1) Within the limits of funds available for such purpose, the Secretary may award grants under this subpart for project costs to applicants with approvable applications therefor which will, in his judgment, best promote the purposes of section 1625 of the Act, taking into consideration—

(i) The severity and seriousness of the safety hazard, licensure or accreditation problem or problems.

(ii) The relative need of the population to be served for the services to be provided, including the availability of alternatives for meeting the need.

(iii) The financial need of the applicant.

(iv) The extent to which the facility will serve persons below the poverty level, as determined by the Secretary of Commerce.

(v) The extent to which the project will foster cost containment or improve the quality of care through enhanced efficiency and productivity.

(2) Priority for funding shall be based on the extent to which services will be made available relative to the cost of the project.

(b) The amount of any grant under this subpart may not exceed 75 percent of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may, as determined by the Secretary, cover up to 100 percent of such costs.

(c) If an applicant has not entered into a legally enforceable fixed price contract for the project for which funds are awarded under this subpart within 180 days of the date of the grant award, the grant award will automatically become null and void.

(d) Where a grant has been awarded to an applicant under this subpart on the condition that any applicable certificates of need and section 1122 finding required under § 124.4(f) will be provided, if such certificates and finding have not been received by the Secretary within 180 days of the grant award, the grant award will automatically become null and void.

§ 124.6 Grant payments.

Grant payments shall be made to the applicant in accordance with the requirements of Subpart K of 45 CFR Part 74.

§ 124.7 Use of grant funds.

Any funds granted pursuant to this subpart, as well as funds assured by the applicant for the project, shall be expended solely for carrying out the approved project in accordance with section 1625 of the Act, the regulations of this subpart, the terms and conditions of the grant award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

§ 124.8 Grantee accountability.

(a) *Records requirements.* (1) Applicants who have received Federal assistance under this subpart shall maintain, in accounting records which are separate from the records of all other funds, records which fully disclose the following:

(i) The amount of all payments received from the Secretary under this subpart,

(ii) Amounts and sources of all funds, in addition to funds received under this subpart, applied to the construction or modernization project funded under this subpart,

(iii) Disposition of all funds for the construction or modernization project funded under this subpart,

(iv) Total cost of the project approved under this subpart, and

(2) Upon request, applicants shall make such records, books, papers, or other documents available to the Secretary and the Comptroller General of the United States or any of their duly authorized representatives which, in their opinion, may be related or pertinent to the grant under this subpart.

(b) *Annual financial statement.* An applicant who receives grant assistance under this subpart shall, not later than 120 days after the end of its fiscal year, unless a longer period is approved by the Secretary for good cause shown, file an annual financial statement which meets the requirements of section 1634 of the Act.

§ 124.9 Non-discrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in that particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing section 504 has been issued (45 CFR Part 84 (42 FR 22676, May 4, 1977)).

(c) All portions and services of the entire facility for the construction or modernization of which, or in connection with which aid under the Act is sought must be made available without discrimination on account of creed and the applicant may not discriminate against any qualified person on account of creed with respect to the privilege of professional practice in the facility.

(d) Attention is also called to the requirements of Title IX of the Education amendments of 1972 and in particular to section 901 of such Act (20 U.S.C. 1681) which provides that no person in the United States shall, on the basis of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance (45 CFR Part 86).

(e) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, which provides that alcohol abusers and alcoholics who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their alcohol abuse or alcoholism by any private or public general hospital that receives support in any form from any federally funded program.

(f) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 407 of the Drug Abuse Office and Treatment Act of 1972, as amended, which provides that drug abusers who are suffering from medical conditions shall not be discriminated against because of their drug abuse or drug dependence, by any private or public general hospital that receives support in any form from any federally funded program.

§ 124.10 Additional conditions.

The Secretary may impose additional conditions prior to or at the time of any grant award when in the Secretary's judgment such conditions are necessary to assure or protect advancement of the project in accordance with the purposes of the Act and the regulations of this subpart or the conservation of grant funds.

§ 124.11 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of that Part 74, except to the extent inconsistent with this subpart. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash depositories.
C Bonding and insurance.
F Grant-related income.
G Matching and cost sharing.
L Budget revision procedures.
M Grant closeout, suspension, and termination.
O Property.
P Procurement standards.
Q Cost principles.

Subpart B—[Reserved]

Subpart C—Standards of Construction, Modernization, and Equipment

SOURCE: 43 FR 45739, Oct. 3, 1978, unless otherwise noted.

§ 124.200 Applicability.

The provisions of this subpart apply to all applications for construction, modernization, or conversion assistance under this part.

§ 124.201 General requirements.

Plans and specifications for each project submitted to the Secretary of Health and Human Services shall be prepared in accordance with "Minimum Requirements of Construction and Equipment for Hospital and Medical Facilities" (DHHS Publication No. (HRA) 78-14012), which is hereby incorporated by reference and deemed published herein. This document is available to interested persons upon request to the Division of Resources Development, Bureau of Health Planning and Resources Development, Health Resources Administration, Department of Health and Human Services or to the Department's regional offices as listed in 45 CFR 5.31. The Secretary may approve plans and specifications which contain deviations from the requirements prescribed in DHHS publication No. (HRA) 78-14012 if he is satisfied that the purposes of the requirements have been fulfilled.

§ 124.202 Conformity to State and local requirements.

The design and construction covered by the plans and specifications must conform to the applicable State and local laws, codes, and ordinances and to the approved State medical facilities plan. The plans and specifications must be complete and adequate for contract purposes and, except for projects assisted under section 1625 of the Act, have the approval and recommendation of the State health planning and development agency designated under section 1521 of the Act.

§ 124.203 Equipment.

Equipment shall be provided in the kind and to the extent necessary for the proper functioning of the facility as planned.

Subparts D–E—[Reserved]

Subpart F—Reasonable Volume of Uncompensated Services to Persons Unable To Pay

AUTHORITY: Sec. 215, 1525, 1602(6), Public Health Service Act as amended; 58 Stat. 690, 88 Stat. 2249, 2259; (42 U.S.C. 216, 300m-4, 300o-1(6)).

SOURCE: 44 FR 29375, May 18, 1979, unless otherwise noted.

§ 124.501 Applicability.

(a) The provisions of this subpart apply to any recipient of Federal assistance under Title VI or XVI of the Public Health Service Act that gave an assurance that it would make available, in the facility or portion of the facility constructed, modernized or converted with that assistance, a reasonable volume of services to persons unable to pay for the services.

(b) The provisions of this subpart apply to facilities for the following periods:

(1) *Facilities assisted under Title VI.* Except where the deficit and excess compliance provisions provide for a longer or shorter period, a facility assisted under Title VI of the Act shall provide uncompensated services at the annual compliance level required by § 124.503(a) for:

(i) Twenty years after the completion of construction, in the case of a facility for which the Secretary provided grant assistance under section 606 of the Act; or

(ii) The period from completion of construction until the amount of a direct loan under sections 610 or 623 of the Act, or the amount of a loan with respect to which the Secretary provided a guarantee and interest subsidy under section 623 of the Act, is repaid, in the case of a facility for which such a loan was made.

(iii) "Completion of construction" means:

(A) The date on which the Secretary determines the facility was opened for service;

(B) If the opening date is not available, it means the date on which the Secretary approved the final part of the facility's application for assistance under Title VI of the Act;

(C) If the date of final approval is not available, it means whatever date the Secretary determines most reasonably approximates the date of final approval.

(2) *Facilities assisted under Title XVI.* The provisions of this subpart apply to a facility assisted under Title XVI of the Act at all times following the Secretary's approval of the facility's application for assistance under Title XVI, except that if the facility does not at the time of that approval provide health services, the assurance applies at all times following the facility's initial provision of health services to patients, as determined by the Secretary.

§ 124.502 Definitions.

As used in this subpart—

"Act" means the Public Health Service Act, as amended.

"Allowable credit" for services provided to a specific patient means the lesser of the facility's usual charge for those services, or the usual charge multiplied by the percentage which the total allowable cost as reported by the facility in the facility's preceding fiscal year under Title XVIII of the Social Security Act (42 U.S.C. 1395) and Subpart D of the implementing regulations (42 CFR 405.401 *et seq.*)

bears to the facility's total patient revenues for the year.

"Applicant" means a person who requests uncompensated services or on whose behalf uncompensated services are requested.

"Facility" means an entity that received assistance under Title VI or XVI of the Act and provided an assurance that it would provide a reasonable volume of services to persons unable to pay for the services.

"Federal assistance" means assistance received by the facility under Title VI or Title XVI of the Act and any assistance supplementary to that Title VI or Title XVI assistance received by the facility under any of the following acts: the District of Columbia Medical Facilities Construction Act of 1968, 82 Stat. 631 (Pub. L. 90-457); the Public Works Acceleration Act of 1962 (42 U.S.C. 2641, *et seq.*); the Public Works and Economic Development Act of 1965 (42 U.S.C. 3121, *et seq.*); the Appalachian Regional Development Act of 1965, as amended (40 U.S.C. App.); the Local Public Works Capital Development and Investment Act of 1976 (Pub. L. 94-369). In the case of a loan guarantee with interest subsidy, or a direct loan sold and guaranteed by the Secretary with an interest subsidy, the amount of Federal assistance under Title VI or Title XVI for a fiscal year is the total amount of the interest subsidy that the Secretary will have paid by the close of that fiscal year, as well as any other payments which the Secretary has made as of the beginning of the fiscal year on behalf of the facility in connection with the loan guarantee or the direct loan which has been sold.

"Fiscal year" means the facility's fiscal year.

"Health Systems Agency" or "HSA" means an agency fully or conditionally designated by the Secretary under section 1515 of the Act.

"Operating costs" for any fiscal year means the total operating expenses of a facility as set forth in an audited financial statement, minus the amount of reimbursement, if any, received (or if not received, claimed) in that year under Titles XVIII and XIX of the Social Security Act.

"Persons unable to pay" means persons who meet the income criteria set out in § 124.506 of this subpart.

"Request for uncompensated services" means any indication by or on behalf of an individual seeking services of the facility of the individual's inability to pay for services. A request for uncompensated services may be made at any time, including following institution of a collection action against the individual.

"Secretary" means the Secretary of Health and Human Services or his delegatee.

"State agency" means the agency of a State fully or conditionally designated by the Secretary as the State health planning and development agency under section 1521 of the Act.

"Uncompensated services" means services that are made available to persons unable to pay for them without charge or at a charge which is less than the allowable credit for those services. The amount of uncompensated services provided in a fiscal year is the total allowable credit for services less the amount charged for the services following an eligibility determination. In determining the amount of uncompensated services, the Secretary includes only those services provided to individuals with respect to whom the facility has made a written determination of eligibility.

§ 124.503 Compliance level.

(a) *Annual compliance level.* (1) A facility is in compliance with its assurance to provide a reasonable volume of services to persons unable to pay if it provides for the fiscal year uncompensated services at a level not less than the lesser of—

(i) Three percent of its operating costs for the most recent fiscal year for which an audited financial statement is available; or

(ii) Ten percent of all Federal assistance provided to or on behalf of the facility, adjusted by a percentage equal to the percentage change in the national Consumer Price Index for medical care between the year in which the facility received assistance or 1979, whichever is later, and the most recent year for which a published Index is available. For purposes of this paragraph, the Federal assistance in the case of a loan which is guaranteed or made and sold by the Secretary will be deemed to have been provided in the year in which the Secretary made the loan.

(b) *Deficit in compliance*— (1) *Facilities assisted under Title VI*—If in any fiscal year a facility assisted under Title VI of the Act fails to meet its annual compliance level, it shall provide uncompensated services in an amount sufficient to make up that deficit (as adjusted under paragraph (d)). The facility may make up a deficit at any time during its period of obligation or in the year or years (if necessary) immediately following, except where the facility failed to provide uncompensated services at the required level although financially able to do so, or where the facility did not comply with the requirements of this subpart.

(2) *Facilities assisted under Title XVI.* If in any fiscal year a facility assisted under Title XVI of the Act fails to meet its annual compliance level but has otherwise complied with the requirements of this subpart, the amount of uncompensated services provided in that year constitutes compliance with this subpart.

(c) *Excess compliance.* (1) Whenever a facility provides in a fiscal year uncompensated services in an amount exceeding its annual compliance level, it may apply the amount of excess (as adjusted under paragraph (d)) to reduce its annual compliance level in any subsequent fiscal year. The facility may use any excess amount to reduce its annual compliance level only if the services in excess of the annual compliance level are provided in accordance with the requirements of this subpart.

(2) A facility assisted under Title VI may in any fiscal year apply the amount of excess credited under this paragraph to satisfy the remainder of its obligation to provide uncompensated services. In any fiscal year, the amount of uncompensated services required to satisfy the remainder of the facility's obligation is its annual compliance level for that fiscal year provided multiplied by the number of years remaining in its period of obligation, plus any deficits required to be made up under this section.

(d) *Calculation and adjustment of deficit and excess.* (1) The amount of a deficit or excess in uncompensated services in any fiscal year is the difference between the facility's annual compliance level for that year and the amount of uncompensated services the facility provided in that year.

(2) The amount of any deficit the facility makes up, and the amount of any excess compliance applied to reduce a facility's annual compliance level, must be adjusted by a percentage equal to the percentage change in the National Consumer Price Index for medical care between the fiscal year in which the facility had a deficit or provided the excess, and the fiscal year in which the facility makes up the deficit or applies the excess to reduce its annual compliance level or satisfy its remaining obligations.

§ 124.504 Affirmative action requirement.

(a) A facility that fails to meet its annual compliance level in any fiscal year shall adopt and implement an affirmative action plan, except where it claims and reports to the Secretary that it was financially unable to provide uncompensated services at the annual compliance level.

(b) The affirmative action plan must include provisions that reasonably can be expected to enable the facility to meet its annual compliance level. An affirmative action plan may include, among other approaches devised by the facility;

(1) Wide notice of the availability of uncompensated services at the facility. Notice under this paragraph may include:

(i) Publication of notices in newspapers of general circulation in the area;

(ii) Announcement of the availability of uncompensated services in other communication media in the area (such as radio and television stations); and

(iii) Notification of the availability of uncompensated services to organizations in the area that would be likely to refer persons in need tof uncompensated services to the facility (such as legal services organizations, community action agencies, and other public and private social services agencies).

(2) If the facility's allocation plan restricts the types of services that will be provided as uncompensated services, or restricts uncompensated services to persons in Category A, expansion of the allocation plan to include other types of services or persons in Category B.

(3) Expansion of the area served by the facility for the purpose of providing uncompensated services; and

(4) Establishment of arrangements with other providers of health care under which those providers (if willing and able to do so) will refer to the facility persons requesting uncompensated services.

(c) The facility shall implement its affirmative action plan when it submits it to the Secretary under § 124.510(a), and shall provide uncompensated services in accordance with the plan, incorporating any changes the Secretary may require, until the annual compliance level is reached in a fiscal year.

§ 124.505 Notice of availability of uncompensated services.

(a) *Published notice.* A facility shall, no later than 60 days before the beginning of its fiscal year, publish in a newspaper of general circulation in its area notice of its uncompensated services obligation. The notice shall include, at a minimum:

(1) The plan of allocation the facility proposes to adopt;

(2) The amount of uncompensated services the facility intends to make available in the fiscal year or a statement that the facility will provide uncompensated services to all persons unable to pay who request uncompensated services; and

(3) An explanation if the amount of uncompensated services the facility intends to make available in a fiscal year is less than the annual compliance level, either because it is not financially able to meet this level or because it has credited excess compliance from another fiscal year. If a facility has satisfied its remaining uncompensated services obligation since the last published notice under this paragraph, or will satisfy the remaining obligation during the fiscal year, the explanation must include this information.

(b) *Notice to HSA.* (1) The facility shall simultaneously provide a copy of the notice under paragraph (a) to the HSA for the area. The HSA may seek public comment, comment to the facility on the extent to which the allocation plan will or will not meet community needs, or take any other appropriate action.

(2) The facility may revise the plan published under paragraph (a) based on comments received from the HSA or the public. The facility shall send a copy of the plan as adopted to the HSA at the beginning of the fiscal year.

(3) A facility may change its allocation plan during a fiscal year after providing notice to the HSA of the revised plan.

(c) *Posted notice.* (1)(i) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas in the facility, including but not limited to the admissions area, the business office and the emergency room.

(ii) If in the service area of the facility the "usual language of households" of ten percent or more of the population, according to the most recent figures published by the Bureau of the Census, is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to, and posted with, those supplied under paragraph (c)(1)(i) of this section.

(iii) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

(2) If a facility determines that it has provided uncompensated services in an amount sufficient to meet its annual compliance level for the fiscal year or its allocation for any period specified in its allocation plan, and that it will not continue to provide uncompensated services during the fiscal year of the appropriate period, it may post an additional notice stating that it has satisfied its obligation for the fiscal year or appropriate period, and

when additional uncompensated services will be available.

(d) *Individual notice.* (1) In any period during a fiscal year in which uncompensated services are available in the facility, the facility shall provide individual written notice of the availability of uncompensated services to each person who seeks services in the facility on behalf of himself or another. The individual written notice must:

(i) State that the facility is required by law to provide a reasonable amount of care without or below charge to people who cannot afford care;

(ii) Set forth the criteria the facility uses for determining eligibility for uncompensated services (in accordance with the financial eligibility criteria and the allocation plan);

(iii) State the location in the facility where anyone seeking uncompensated services may request them; and

(iv) State that the facility will make a written determination of whether the person will receive uncompensated services, within two working days of a request for uncompensated services.

(2) The facility shall provide the individual written notice before providing services, except where the emergency nature of the services provided makes prior notice impractical. If this exception applies, the facility shall provide the written notice to next of kin or to the patient as soon as practical, but not later than when first presenting a bill for services.

(3) The facility shall make reasonable efforts to communicate the contents of the individual written notice to persons who it has reason to believe cannot read the notice.

§ 124.506 Financial eligibility criteria for identifying persons unable to pay.

(a) A person unable to pay for health services is a person who falls into either of the following categories:

(1) *Category A*—A person whose individual or family income, as applicable, for the 12 months preceding the determination of eligibility is not more than the current poverty income guideline of the Community Services Administration (as set forth in 45 CFR 1060.2-1 *et seq.*) that applies to the individual or family. The facility shall provide uncompensated services to persons in this category without charge.

(2) *Category B*—A person whose individual or family income, as applicable, for the 12 months preceding the determination of eligibility is greater than the current poverty income guideline of the Community Services Administration (as set forth in 45 CFR 1060.2-1 *et seq.*) that applies to the individual or family but not more than twice that guideline. If persons in Category B are included in the allocation plan, the facility shall provide uncompensated services to these persons without charge, or in accordance with a schedule of charges, as specified in the allocation plan.

(b) A person is eligible for uncompensated services if his annual income is at or below the level established under paragraph (a) when calculated by either of the following methods:

(1) Multiplying by four the person's income for the three months preceding the determination of eligibility; or

(2) Using the person's actual income for the 12 months preceding the determination of eligibility.

§ 124.507 Allocation of services: plan requirement.

(a) A facility shall provide its uncompensated services in accordance with a plan that sets out a method by which the facility will distribute its uncompensated services among persons unable to pay. In developing its plan the facility shall take into consideration comments it receives from the HSA or others with respect to community need. The plan must:

(1) Include the type of services that will be made available;

(2) Specify the method, if any, for distibuting those services in different periods of the year;

(3) State whether persons eligible under Category B criteria will be provided uncompensated services, and if so, whether the services will be available without charge or at a reduced charge;

(4) If services will be made available to Category B persons at a reduced charge, specify the method used for reducing charges, and provide that

this method is applicable to all persons in Category B; and

(5) Provide that the facility provides uncompensated services to all persons eligible under the plan who request uncompensated services.

(b) A facility may adopt any allocation plan that meets the requirements of paragraph (a). If the facility fails to adopt and publish a plan as required by § 124.505 it will be presumed to have adopted a plan under which it provides all services of the facility without charge to all persons unable to pay who first request such services, until its annual compliance level has been met for the fiscal year.

§ 124.508 Determinations of eligibility.

(a) *Determinations.* In any period or periods in a fiscal year in which uncompensated services are available, the facility shall make a determination of eligibility for uncompensated services within two working days following the request for uncompensated services. The facility shall give the applicant a copy of the determination promptly.

(b) *Content of favorable determinations.* A determination that an applicant is eligible must indicate:

(1) That the facility will provide uncompensated services at no charge or at a specified charge less than the allowable credit for the services;

(2) The date on which services were requested;

(3) The date on which the determination was made;

(4) The income of the applicant; and

(5) The date on which services were or will be first provided to the applicant.

(c) *Reasons for denial.* The facility shall provide each applicant who requests uncompensated services and is denied them, in whole or in part, a written and dated statement of the reasons for the denial when the denial is made. This requirement applies throughout the facility's fiscal year.

(d) *Verification.* A facility may, as a condition to providing uncompensated services to any applicant, require the applicant to furnish any information that is reasonably necessary to substantiate the applicant's income.

§ 124.509 Exclusions from uncompensated services.

A facility may not include the following in computing the uncompensated services it provides:

(a) Any amount that the facility has received, or is entitled to receive, from a third party insurer or under a governmental program, except where the person to whom the facility provides services refused to take reasonable actions necessary to obtain the entitlement.

(b) Any amount in excess of the payment that the facility has received, or is entitled to receive, from a third party insurer or under a governmental program where the facility has agreed or is otherwise required to accept this payment as payment in full for the services;

(c) Any amount for services provided 96 hours or more following notification to the facility by a professional standards review organization (PSRO) that the PSRO disapproved the services under section 1155(a)(1) of the Social Security Act; and

(d) Any amount for which reimbursement would be available under a governmental program (such as medicare or medicaid) in which the facility, although eligible to do so, and required by § 124.603(c)(1) to do so, does not participate.

§ 124.510 Reporting and record maintenance requirements.

(a) *Reporting requirements*—(1) *Timing of reports*—(i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary.

(ii) A facility shall submit the required report more frequently than once every three years under the following circumstances:

(A) If the facility determines that in the preceding fiscal year it did not provide uncompensated services at the annual compliance level, it shall submit a report in the fiscal year in which the deficit is determined.

(B) If the Secretary determines, and notifies the facility in writing, that a report is needed for proper administration of the program, the facility shall submit a report within 90 days after receiving notice from the Secretary, or within 90 days after the close of the fiscal year, whichever is later.

(iii) Except as specified in paragraph (a)(ii)(B) of this section, the reports required by this section shall be submitted within 90 days after the close of the fiscal year, unless a longer period is approved by the Secretary for good cause.

(2) *Content of report.* The report must include the following information, in a form prescribed by the Secretary:

(i) Information that the Secretary prescribes to permit a determination of whether a facility has met the annual compliance level for the fiscal years covered by the report;

(ii) The date on which the notice required by § 124.505(a) was published and sent to the HSA for the area, and the name of the newspaper that printed the notice;

(iii) If the amount of uncompensated services provided by the applicant in the preceding fiscal year was lower than the annual compliance level, an explanation of why the facility did not meet the required level. If the facility claims that it failed to meet the required compliance level because it was financially unable to do so, it shall explain and document its claim;

(iv) If the facility is required to submit an affirmative action plan, a copy of the plan. If an affirmative action plan was in effect during the preceding fiscal year, documentation of actions taken to implement the plan; and

(v) Other information that the Secretary prescribes.

(3) A facility shall provide a copy of any report to the HSA for the area when submitting it to the Secretary.

(4) *Institution of suit.* Not later than 10 days after being served with a summons or complaint, the facility shall notify the Regional Health Administrator for the Region of HHS in which it is located of any legal action brought against it alleging that it has failed to comply with the requirements of this subpart.[1]

(b) *Record maintenance requirements.* (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the requirements of this subpart in any fiscal year, including:

(i) Any documents from which the information required to be reported under paragraph (a) of this section was obtained;

(ii) Accounts which clearly segregate uncompensated services from other accounts; and

(iii) Copies of the determinations of eligibility under § 124.508(b).

A facility shall maintain these records until 180 days following the close of the Secretary's investigation under § 124.511(a).

(2) In any fiscal year a facility may stop providing individual written notice, and may stop making eligibility determinations, only if it maintains records that document on a current basis that it has met its annual compliance level for the fiscal year or appropriate period specified in its allocation plan.

(3) A facility shall, within 60 days of the end of each fiscal year, ascertain the amount of uncompensated services it provided in that fiscal year. Documents that support the facility's determination shall be made available to the public or the HSA for the area on request. If a report is or will be filed under § 124.510 a facility may respond to a request by providing a copy of the report to the requester.

§ 124.511 Investigation and enforcement.

(a) *Investigations.* (1) The Secretary periodically investigates the compliance of facilities with the requirements of this subpart, and investigates complaints.

(2)(i) A complaint is considered to be filed with the Secretary on the date the following information is received in the Office of the Regional Health

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[1] The addresses of the Regional Offices of HHS are set out in 45 CFR 5.31.

Administrator for the Region of HHS in which the facility is located:

(A) The name and address of the person making the complaint or on whose behalf the complaint is made;

(B) The name and location of the facility;

(C) The date or approximate date on which the event complained of occurred; and

(D) A statement of what actions the complainant considers to violate the requirements of this subpart.

(ii) The Secretary promptly provides a copy of the complaint to the facility named in the complaint.

(3) When the Secretary investigates a facility, the facility shall provide to the Secretary on request any documents, records and other information concerning its operations that relate to the requirements of this subpart.

(4) Section 1612(c) of the Act provides that if the Secretary dismisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the complaint is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, he may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the applicant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Enforcement.* (1) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility did not comply with the requirements of this subpart, he may take any action authorized by law to secure compliance, including but not limited to voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(2) A facility that has denied uncompensated services to any person because it failed to comply with the requirements of this subpart will not be in compliance with its assurance until it takes whatever steps are necessary to remedy fully the noncompliance.

(3)(i) If in a fiscal year a facility fails to provide uncompensated services in an amount sufficient to meet its compliance level, and the Secretary determines—

(A) That, contrary to the report filed under § 124.510, the facility was financially able to provide some or all of the deficit amount in the fiscal year in question; or

(B) That the deficit was due to the facility's failure to comply with a requirement of this subpart—the facility shall provide uncompensated services in an amount sufficient to make up the deficit in the fiscal year following the finding, unless the Secretary determines that it is financially unable to do so. If the Secretary determines that the facility is not financially able to provide all of the deficit in the fiscal year following the finding, the Secretary sets a compliance level for that year and subsequent years that permits the deficit to be made up in as short a period of time as he determines is consistent with the financial stability of the facility. Any deficit is calculated and adjusted in accordance with § 124.503(d).

(ii) Where a facility indicates in its published notice that it will provide uncompensated services in an amount below the annual compliance level because of a financial inability to meet the annual compliance level, and the Secretary determines during the fiscal year that the facility is financially able to provide additional uncompensated services, he may require the facility to provide additional appropriate amounts of uncompensated services during the fiscal year.

(iii) In determining whether a facility was or is financially able to meet its annual compliance level, the Secretary will consider factors such as:

(A) The ratio of revenues to expenses;

(B) The occupancy rate;

(C) The ratio of current assets to current liabilities;

(D) The average cost per patient day;

(E) The number of days of operating expenses in accounts payable;

(F) The number of days of revenues in accounts receivable;

(G) The sinking fund (or depreciation fund) balance;

(H) The debt coverage ratio; and

(I) The availability of restricted or unrestricted funds (such as an endowment) available for charitable use. In making this determination the Secretary will consider any comments submitted by the HSA for the area or by other persons.

(4)(i) Where a facility submits an affirmative action plan, the Secretary reviews the plan. If the Secretary determines that the plan is inadequate, he notifies the facility of additional actions it shall incorporate into the plan, including but not limited to, any of the illustrative approaches listed in § 124.504(b).

(ii) In determining whether an affirmative action plan is acceptable, the Secretary will consider any comments submitted by the HSA for the area or by other persons.

§ 124.512 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart, and the State agency is able and willing to do so, he may enter into an agreement with the State agency for the State agency to assist him in administering this subpart in the State. An agreement may be terminated by the Secretary or the State agency on 60 days' notice.

(b) Under an agreement, the State agency will provide the Secretary with any assistance he requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints regarding noncompliance;

(2) Monitoring of the compliance of facilities with the requirements of this subpart;

(3) Review of affirmative action plans submitted under § 124.504;

(4) Review of reports submitted under § 124.510;

(5) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary or review by the Secretary on his own initiative; and

(6) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) A State agency may use funds received under section 1525 of the Act to pay for expenses incurred in the course of carrying out this agreement.

(d) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of uncompensated services by facilities in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

Subpart G—Community Service

AUTHORITY: Sec. 215, 1525, 1602(6), Public Health Service Act as amended; 58 Stat 690, 88 Stat. 2249, 2259; 42 U.S.C. 216, 300m-4, 300o-1(6).

SOURCE: 44 FR 29379, May 18, 1979, unless otherwise noted.

§ 124.601 Applicability.

The provisions of this subpart apply to any recipient of Federal assistance under Title VI or XVI of the Public Health Service Act that has given an assurance that it would make the facility or portion thereof assisted available to all persons residing (and, in the case of Title XVI assisted applicants, employed), in the territorial area it serves. This assurance is referred to in this subpart as the "community service assurance."

§ 124.602 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Facility" means the an entity that received assistance under Title VI or Title XVI of the Act and provided a community service assurance.

"Fiscal year" means facility's fiscal year.

"Secretary" means the Secretary of Health and Human Services or his delegatee.

"Service area" means the geographic area designated as the area served by the facility in the most recent State plan approved by the Secretary under Title VI, except that, at the request of the facility, the Secretary may designate a different area proposed by the facility when he determines that a different area is appropriate based on the criteria in 42 CFR 53.1(d).

"State agency" means the agency of a state fully or conditionally designated by the Secretary as the State health planning and development agency of the State under section 1521 of the Act.

§ 124.603 Provision of services.

(a) *General.* (1) In order to comply with its community service assurance, a facility shall make the services provided in the facility or portion thereof constructed, modernized, or converted with Federal assistance under Title VI or XVI of the Act available to all persons residing (and, in the case of facilities assisted under Title XVI of the Act, employed) in the facility's service area without discrimination on the ground of race, color, national origin, creed, or any other ground unrelated to an individual's need for the service or the availability of the needed service in the facility. Subject to paragraph (b) (concerning emergency services) a facility may deny services to persons who are unable to pay for them unless those persons are required to be provided uncompensated services under the provisions of Subpart F.

(2) A person is residing in the facility's service area for purposes of this section if the person:

(i) Is living in the service area with the intention to remain there permanently or for an indefinite period;

(ii) Is living in the service area for purposes of employment; or

(iii) Is living with a family member who resides in the service area.

(b) *Emergency services.* (1) A facility may not deny emergency services to any person who resides (or, in the case of facilities assisted under Title XVI of the Act, is employed) in the facility's service area on the ground that the person is unable to pay for those services.

(2) A facility may discharge a person that has received emergency services, or may transfer the person to another facility able to provide necessary services, when the appropriate medical personnel determine that discharge or transfer will not subject the person to a substantial risk of deterioration in medical condition.

(c) *Third party payor programs.* (1) The facility shall make arrangements, if eligible to do so, for reimbursement for services with:

(i) Those principal State and local governmental third-party payors that provide reimbursement for services that is not less than the actual costs, as determined in accordance with accepted cost accounting principles; and

(ii) Federal governmental third-party programs, such as medicare and medicaid.

(2) The facility shall take any necessary steps to insure that admission to and services of the facility are available to beneficiaries of the governmental programs specified in paragraph (c)(1) of this section without discrimination or preference because they are beneficiaries of those programs.

(d) *Exclusionary admissions policies.* A facility is out of compliance with its community service assurance if it uses an admission policy that has the effect of excluding persons on a ground other than those permitted under paragraph (a) of this section. Illustrative applications of this requirement are described in the following paragraphs:

(1) A facility has a policy or practice of admitting only those patients who are referred by physicians with staff privileges at the facility. If this policy or practice has the effect of excluding persons who reside (or for Title XVI facilities, are employed) in the community from the facility because they do not have a private family doctor with staff privileges at the facility, the facility would not be in compliance with its assurance. The facility is not required to abolish its staff physician admissions policy as a usual method for admission. However, to be in compliance with its community service assurance it must make alternative arrangements to assist area residents who would otherwise be unable to gain admission to obtain services available in the facility. Examples of alternative arrangements a facility might use include:

(i) Authorizing the individual's physician, if licensed and otherwise qualified, to treat the patient at the facility even though the physician does not have staff privileges at the facility;

(ii) For those patients who have no physician, obtaining the voluntary agreement of physicians with staff privileges at the facility to accept referrals of such patients, perhaps on a rotating basis;

(iii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iv) Establishing a hospital-based primary care clinic through which patients needing hospitalization may be admitted; or

(v) Hiring or contracting with qualified physicians to treat patients who do not have private physicians.

(2) A facility, as required, is a qualified provider under the Title XIX medicaid program, but few or none of the physicians with staff privileges at the facility or in a particular department or sub-department of the facility will treat medicaid patients. If the effect is that some medicaid patients are excluded from the facility or from any service provided in the facility, the facility is not in compliance with its community service assurance. To be in compliance a facility does not have to require all of its staff physicians to accept medicaid. However, it must take steps to ensure that medicaid beneficiaries have full access to all of its available services. Examples of steps that may be taken include:

(i) Obtaining the voluntary agreement of a reasonable number of physicians with staff privileges at the facility and in each department or sub-department to accept referral of medicaid patients, perhaps on a rotating basis;

(ii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iii) Establishing a clinic through which medicaid beneficiaries needing hospitalization may be admitted; or

(iv) Hiring or contracting with physicians to treat medicaid patients.

(3) A facility requires advance deposits (pre-admission or pre-service deposits) before admitting or serving patients. If the effect of this practice is that some persons are denied admission or service or face substantial delays in gaining admission or service solely because they do not have the necessary cash on hand, this would constitute a violation of the community service assurance. While the facility is not required to forego the use of a deposit policy in all situations, it is required to make alternative arrangements to ensure that persons who probably can pay for the services are not denied them simply because they do not have the available cash at the time services are requested. For example, many employed persons and persons with other collateral do not have savings, but can pay hospital bills on an installment basis, or can pay a small deposit. Such persons may not be excluded from admission or denied services because of their inability to pay a deposit.

§ 124.604 Posted notice.

(a) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas of the facility, including but not limited to the admissions area, the business office and the emergency room.

(b) If in the service area of the facility the "usual language of households" of ten percent or more of the population, according to the most recent figures published by the Bureau of the Census, is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to, and posted with, those supplied under paragraph (a).

(c) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

§ 124.605 Reporting and record maintenance requirements.

(a) *Reporting requirements*—(1) *Timing of reports*—(i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary. The report required by this section shall be submitted not later than 90 days after the end of the fiscal year, unless a longer period is approved by the Secretary for good cause shown.

(ii) A facility shall also submit the required report whenever the Secretary determines, and so notifies the facility in writing, that a report is needed for proper administration of the program. In this situation the facility shall submit the report specified in this section for the filing of reports, within 90 days after receiving notice from the Secretary, or within 90 days after the close of the fiscal year, whichever is later.

(2) *Content of report.* The report must be submitted on a form prescribed by the Secretary and must include information that the Secretary prescribes to permit a determination of whether a facility has met its obligations under this subpart.

(3) The facility shall provide a copy of any report to the HSA for the area when submitting it to the Secretary.

(4) *Institution of suit.* Not later than 10 days after being served with a summons or complaint, the applicant shall notify the Regional Health Administrator for the Region of HHS in which it is located of any legal action brought against it alleging that it has failed to comply with the requirements of this subpart.[1]

(b) *Record maintenance requirements.* (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance requirements of this subpart in any fiscal year, including documents from which information required to be reported under paragraph (a) of this section was obtained. A facility shall maintain these records until 180 days following the close of the Secretary's investigation under § 124.606(a).

§ 124.606 Investigation and enforcement.

(a) *Investigations.* (1) The Secretary periodically investigates the compliance of facilities with the requirements of this subpart, and investigates complaints.

(2)(i) A complaint is filed with the Secretary on the date on which the following information is received in the Office of the Regional Health Administrator for the Region of HHS in which the facility is located:

(A) The name and address of the person making the complaint or on whose behalf the complaint is made;

(B) The name and location of the facility;

(C) The date or approximate date on which the event complained of occurred, and

(D) A statement of what actions the complainant considers to violate the requirements of this subpart.

(ii) The Secretary promptly provides a copy of the complaint to each facility named in the complaint.

(3) When the Secretary investigates a facility, the facility shall provide to the Secretary on request any documents, records and other information concerning its operations that relate to the requirements of this subpart.

(4) The Act provides that if the Secretary dismisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the complaint is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, he may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the complainant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier

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[1] The addresses of the Regional Office of HHS are set out in 45 CFR 5.31.

than 45 days after the complaint is filed.

(b) *Enforcement.* (1) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility did not comply with the requirements of this subpart, he may take any action authorized by law to secure compliance, including but not limited to voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(2) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility has limited the availability of its services in a manner proscribed by this subpart, he may, in addition to any other action that he is authorized to take in accordance with the Act, require the facility to establish an effective affirmative action plan that in his judgment is designed to insure that its services are made available in accordance with the requirements of this subpart.

§ 124.607 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart, and the State agency is able and willing to do so, he may enter into an agreement with the State agency for the State agency to assist him in administering this subpart in the State.

(b) Under an agreement, the State agency will provide the Secretary with any assistance he requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints of noncompliance;

(2) Monitoring the compliance of facilities with the requirements of this subpart;

(3) Review of affirmative action plans submitted under § 124.606(b);

(4) Review of reports submitted under § 124.605;

(5) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary or review by the Secretary on his own initiative; and

(6) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) A State agency may use funds received under section 1525 of the Act to pay for expenses incurred in the course of carrying out this agreement.

(d) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of services by any facility in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

APPENDIX—INTERIM PROCEDURES AND CRITERIA FOR REVIEW BY HEALTH SYSTEMS AGENCIES OF APPLICATIONS UNDER SECTION 1625 OF THE PUBLIC HEALTH SERVICE ACT

In performing reviews under section 1513 (e) of the Public Health Service Act (42 U.S.C. 3001-2(c)) of applications for grants under section 1625 of the Act, health systems agencies shall use the procedures and criteria stated below. A health systems agency may not conduct such reviews until the procedures and criteria to be used in conducting the reviews have been adopted by the agency and published in newspapers of general circulation within the health service area or other public information channels.

PROCEDURES

The procedures adopted and utilized by a health systems agency for conducting reviews of applications for grants under section 1625 of the Act shall include at least the following: 1. Except as provided below, notification of the beginning of a review within seven days of the receipt by the health systems agency of the application. Where the application was received by the health systems agency prior to publication of this subpart in the FEDERAL REGISTER, notification must be made within seven days of the date on which the health systems agency adopts its procedures and criteria. The notification shall include the proposed schedule for the review, the period within which a public hearing during the course of the review may be requested (which must be a reasonable period from the transmittal of the written notification required above), and the manner in which notification will be provided of the time and place of any hearings so requested. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels. Notification to the applicant whose application is being reviewed and all other applicants for assistance under section 1625 of the Act providing health service in the health service area shall be by mail (which may be as part of a newsletter). The health systems agency must simultaneously notify the Federal funding agency of the beginning of the review.

2. Schedules for reviews which provide that such reviews shall not exceed 60 days from the date of notification made in accordance with paragraph 1 of this section to the date of the written findings made in accordance with paragraph 4 of this section. This does not preclude a health systems agency from conducting its review in less than 60 days.

3. Provision for applicants to submit to the health systems agency (in such form and manner as the agency shall require) such information as the agency deems necessary in order to conduct its review.

4. Written findings which state the basis for the approval or disapproval of the application by the health systems agency. Such findings shall be sent to the applicant, the State health planning and development agency (or agencies), and the Secretary, and shall be available to other upon request.

5. Access by the general public to all such applications reviewed by the health systems agency and to all other written materials pertinent to the agency review.

6. Public hearings in the course of agency review, if requested by one or more persons directly affected by the review. For purposes of this paragraph, a "person directly affected by the review" is as defined in 42 CFR 122.306 (a)(7).

CRITERIA

The specific criteria adopted and utilized by a health systems of this agency to conduct reviews of applications for grants under section 1625 of the Act shall include at least the following:

1. The relationship of the health services of the facility to the applicable health systems plan and annual implementation plan.

2. The relationship of the health services of the facility to the long-range development plan (if any) of the applicant.

3. The need that the population served or to be served by the facility has for the health services of such facility.

4. The availability of alternative, less costly, or more effective methods of providing the health services which the facility provides.

5. The relationship of the health services provided by the facility to the existing health care system of the area.

6. The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of services by the facility and the availability of alternative uses of such resources for the provision of other health services.

7. The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas. Such entities may include medical and other health professions schools, multidisciplinary clinics, and other speciality centers.

8. The special needs and circumstances of health maintenance organizations for which assistance may be provided under Title XIII.

9. The costs and methods of the proposed construction or modernization, including the costs and methods of energy provision.

10. The probable impact of the project reviewed on the applicant's costs of providing health services.

CHAPTER III—ST. ELIZABETHS HOSPITAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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PART 300—[RESERVED]

PART 301—DISBURSEMENT OF PENSION MONEY

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AUTHORITY: R.S. 4839, as amended; 24 U.S.C. 165.

SOURCE: 2 FR 1623, Aug. 3, 1937, unless otherwise noted.

§ 301.1 Deposit of money in Treasury.

All moneys received by the Superintendent under the Acts of February 20, 1905 (33 Stat. 731; 24 U.S.C. 195, 165), and February 2, 1909 (35 Stat. 592; 24 U.S.C. 165), shall be scheduled to the Chief Disbursing Officer, Division of Disbursements, Treasury Department, for deposit in the United States Treasury.

§ 301.2 Keeping accounts of money.

Separate accounts shall be kept by the Superintendent with each pensioner showing the amount of money received and expended, and the balance on hand.

§ 301.3 Purposes for which money shall be disbursed.

The pension money shall be disbursed and used for three general purposes, in order as follows:

(a) For the benefit of the pensioner.

(b) For the benefit of relatives entitled under the law.

(c) To reimburse the Hospital for the pensioner's board and maintenance, where no other provision is made therefor.

§ 301.4 Part of funds reserved for use of pensioner.

Irrespective of the amount received as pension and placed to the pensioner's account, at least one-sixth thereof shall be reserved for the use of the pensioner, before any provision is made for payments to relatives or for board.

§ 301.5 Payment of board to St. Elizabeths Hospital.

Where no provision is otherwise made for the payment of the pensioner's board and maintenance in the Hospital from public or special funds under Federal control, the remainder, after setting aside the amounts for relatives specified in §§ 301.7-301.10, shall be used to pay for the pensioner's board and maintenance in the Hospital up to an amount equal to the current monthly rate for board of patients.

§ 301.6 Use of unobligated balance of funds.

Any excess amounts not required for payments to relatives or for board shall be available for the purchase of such articles as may be required for the pensioner's welfare and which are not provided from the regular Hospital funds, or otherwise for the pensioner's benefit.

§ 301.7 Disposition of funds not exceeding $15 per month.

The basic rate of pension being $15 or less per month, one-sixth thereof shall be reserved for the pensioner, to be expended in the purchase of such articles as may be required for the pensioner's welfare and which are not provided from the regular Hospital funds, or otherwise for the pensioner's benefit. The entire remainder will be paid, in the case of a male pensioner, to his dependent wife, minor children, or parents, in the order named; in the case of a female pensioner, to her dependent minor children.

§ 301.8 Disposition of funds greater than $15, and not exceeding $25, per month.

The basic rate of pension being greater than $15 but not exceeding $25 per month, the dependent wife, minor children, or parents, in the order named in the case of a male pensioner, or the dependent minor children, in the case of a female pensioner, shall receive not less than $12.50 per month, the balance to be reserved for the pensioner, to be expended in the purchase of such articles as may be required for the pensioner's welfare and which are not provided from the regular Hospital funds, or otherwise for the pensioner's benefit, subject to provision for payment of board.

§ 301.9 Disposition of funds in excess of $25 per month.

The basic rate of pension being in excess of $25 per month, the dependent wife, minor children, or parents, in the order named in the case of a male pensioner, or the dependent minor children in the case of a female pensioner, shall receive an amount equal to one-half of the entire pension, the balance to be reserved for the pensioner, to be expended in the purchase of such articles as may be required for the pensioner's welfare and which are not provided from the regular Hospital funds, or otherwise for the pensioner's benefit, subject to provision for payment of board.

§ 301.10 Amount available for disbursement to a nondependent relative.

If the wife, minor children, or parents of a male pensioner, or the minor children of a female pensioner, be not in fact dependent upon the pensioner in any degree for support, she or they shall receive no greater than one-half of the amount payable in case of her or their dependence, the balance to be reserved for the pensioner, to be expended in the purchase of such articles as may be required for the pensioner's welfare and which are not provided from regular Hospital funds, or otherwise for the pensioner's benefit, subject to provision for payment of board.

§ 301.11 Use of fund where there are no relatives of certain classes.

If there be no wife, minor children, or parents, in the case of a male pensioner, or minor children in the case of a female pensioner, the entire amount of the pension shall be reserved for the pensioner, to be expended in the purchase of such articles as may be required for the pensioner's welfare and which are not provided from the regular Hospital funds, or otherwise for the pensioner's benefit, subject to provision for payment of board.

§ 301.12 Disposition of balance of fund in case of discharge or death.

Any unexpended balance of pension money reserved for the pensioner's benefit shall be paid, in the event of the pensioner's discharge from the Hospital, to the pensioner, or to his or her lawful guardian, or in the event that the pensioner is returned to a branch of the National Home for Disabled Volunteer Soldiers (now a part of the Veterans Administration), to the treasurer or fiscal officer of such branch for such pensioner, or in the event of the pensioner's discharge from the Hospital and his immediate transfer to the United States Soldiers's Home, to the treasurer of said home. In the event of the pensioner's death while an inmate of the Hospital, the same shall be paid, in the case of a male pensioner, to his widow, or if there be no widow, to his minor children, and in the case of a female pensioner, to her minor children. If there be no widow or minor children entitled to payment of such balance of pension money, it shall be applied to the general uses of the Hospital.

§ 301.13 Questions affecting the rights of claimants for share of pension of inmates.

All questions affecting the right of claimants for a share of the pension of inmates of the Hospital shall be determined upon evidence to be submitted to the United States Veterans Administration. The findings of the United States Veterans Administration upon such evidence shall be submitted for the approval of the Secretary of Health and Human Services, and upon their transmission to the Superintendent of the Hospital with such approval, shall be accepted by him to control the disbursement of the pension under the law and the regulations in this part.

§ 301.14 Table of monthly division of rates of pension made part of regulations.

The following "Table of monthly division of rates of pension under the acts of February 20, 1905, and February 2, 1909," is hereby made a part of the regulations in this part to serve as a guide in determining in each case the respective amounts to be reserved for the pensioner's benefit and to be paid to relatives entitled. Any unusual rates of pension not included will be divided as nearly as may be in the same proportions as therein observed.

TABLE OF MONTHLY DIVISION OF RATES OF PENSION UNDER THE ACTS OF FEBRUARY 20, 1905, AND FEBRUARY 2, 1909

Monthly pension rate	In case of dependent relatives		In case of nondependent relatives		In cases of no dependent relatives
	Pensioner	Relatives	Pensioner	Relatives	Pensioner
$1.00	$0.17	$0.83	$0.58	$0.42	$1.00
$2.00	.33	1.67	1.17	1.83	2.00
$3.00	.50	2.50	1.75	1.25	3.00
$4.00	.67	3.33	2.33	1.67	4.00
$5.00	.83	4.17	2.92	2.08	5.00
$6.00	1.00	5.00	3.50	2.50	6.00
$7.00	1.17	5.83	4.08	2.92	7.00
$8.00	1.33	6.67	4.67	3.33	8.00
$9.00	1.50	7.50	5.25	3.75	9.00
$10.00	1.67	8.33	5.83	4.17	10.00
$11.00	1.83	9.17	6.42	4.58	11.00
$12.00	2.00	10.00	7.00	5.00	12.00
$13.00	2.17	10.83	7.58	5.42	13.00
$14.00	2.33	11.67	8.17	5.83	14.00
$15.00	2.50	12.50	8.75	6.25	15.00
$17.50	5.00	12.50	11.25	6.25	17.50
$20.00	7.50	12.50	13.75	6.25	20.00
$22.50	10.00	12.50	16.25	6.25	22.00
$25.00	12.50	12.50	18.75	6.25	25.00
$30.00	15.00	15.00	22.50	7.50	30.00
$35.00	17.50	17.50	26.25	8.75	35.00
$40.00	20.00	20.00	30.00	10.00	40.00
$45.00	22.50	22.50	33.75	11.25	45.05
$50.00	25.00	25.00	37.50	12.50	50.00
$60.00	30.00	30.00	45.00	15.00	60.00
$75.00	37.50	37.50	56.25	18.75	75.00

PART 302—HANDLING OF PERSONAL FUNDS OF PATIENTS

Sec.
302.1 Accounting for moneys intrusted to the hospital.
302.2 Accounts open to inspection of proper officials.
302.3 Financial Officer shall deposit funds in the United States Treasury.
302.4 Financial Officer authorized to draw funds and make cash payments to patients.
302.5 Report of actions to the Secretary of Health and Human Services.
302.6 Disbursing of trust funds to patients.

AUTHORITY: R.S. 4839, as amended; 24 U.S.C. 165.

SOURCE: Regulations, May 1, 1909, unless otherwise noted.

§ 302.1 Accounting for moneys intrusted to the hospital.

The Financial Officer[1] of the St. Elizabeths Hospital, under the direction of the Superintendent of the Hospital, shall receive and account for all moneys intrusted to the Financial Officer by or for the use of patients.

§ 302.2 Accounts open to inspection of proper officials.

The Financial Officer shall keep, subject at all times to the inspection of the proper officials, a separate account with each patient having personal moneys on deposit, showing the amount received, expended, and the balance of each.

§ 302.3 Financial Officer shall deposit funds in the United States Treasury.

The Financial Officer shall deposit in the United States Treasury, as Financial Officer, not later than at the end of each month, all funds now in hand or which may hereafter be intrusted to the Financial Officer by or for the use of such patients, of which an account shall be kept separate and apart from moneys received on account of pensions, and whose bond in that capacity shall include the faithful custody and disbursement of all funds so received.

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[1] The term "Financial Officer" has been substituted for the term "Disbursing Agent," which appears in the May 1, 1909, regulations, as a result of the issuance of Executive Order 6166, June 10, 1933. The functions of the official remain unchanged so far as the regulations in this chapter are concerned.

§ 302.4 Financial Officer authorized to draw funds and make cash payments to patients.

The Financial Officer is authorized to draw therefrom in the usual manner, from time to time, and to make cash payments upon voucher forms approved by the accounting officers of the Treasury for the use of such patients, not to exceed for any one patient the amount intrusted to the Superintendent on account of such patients.

§ 302.5 Report of actions to the Secretary of Health and Human Services.

The Financial Officer shall, on or before the fifteenth of each month following the quarter for which accounts are rendered, forward to the Secretary of Health and Human Services for transmission to the General Accounting Office a duplicate of the patients' accounts.

§ 302.6 Disbursing of trust funds to patients.

The Financial Officer may, subject to the limitations of the law, draw, as Financial Officer, such sums as in the judgment of the Financial Officer may be necessary for the use of individual patients.

PART 303—DISPOSITION OF MONEYS OF DECEASED INMATES

Sec.
303.1 Search for relatives or friends of patients.
303.2 Manner in which efforts will be made to get information.
303.3 Communication with claimants.
303.4 Character of proof required.
303.5 Conditions under which payments will be made if over $100.
303.6 Conditions under which payments will be made if under $100.
303.7 Rights of relative who has incurred expense for deceased.
303.8 Recognition of an administrator.
303.9 Application of the statute of distributions of the District of Columbia.

AUTHORITY: Sec. 1, 34 Stat. 730 as amended; 24 U.S.C. 177.

SOURCE: Regulations, Apr. 25, 1907, unless otherwise noted.

§ 303.1 Search for relatives or friends of patients.

The records of the hospital will be searched, and a circular letter will be sent to the relatives or friends of deceased whose addresses are shown by the records of the institution, requesting information as to the legal heirs of the deceased. These letters will be sent first to the relatives in the order of their relationship to the deceased; and if no answer is received, then to any friends of the deceased whose addresses are shown by the records.

§ 303.2 Manner in which efforts will be made to get information.

(a) If the legal heirs of deceased cannot be ascertained through data of record in the hospital, application for such information will be made in the following manner:

(b) If the deceased was a pensioner, or was an applicant for pension, or if there is any reason to believe that he may have applied for a pension, a circular letter containing all available data will be sent to the Commissioner of Pensions requesting the information. If the deceased was admitted from the Soldiers' Home, the Naval Home, or a branch of the National Home for Disabled Volunteer Soldiers, or if it is shown that he was at any time an inmate of a State or Territorial home, or other State or Territorial institution, the information will be requested of such home or institution.

(c) If the deceased was admitted from the Army or the Navy, application will be made to the Secretary of War or the Secretary of the Navy, and to the Auditors for such Departments, respectively; and if admitted from the Public Health Service, application will be made to the Secretary of Health and Human Services. Where the former place of residence of deceased is known, an inquiry will be addressed to the postmaster of the town in which he resided; and in all cases the superintendent will adopt any other means to ascertain the whereabouts of the heirs of deceased which seem appropriate to the particular case.

§ 303.3 Communication with claimants.

Upon receiving information as to the address of any person supposed to be an heir of deceased, the superintendent will address a letter to such person informing him of the amount to the credit of the deceased, and inquiring whether he is, solely or jointly with others, the heir of such deceased inmate.

§ 303.4 Character of proof required.

Upon receipt by the hospital of a claim from a person claiming to be the legal heir of the deceased, the character of proof necessary to establish such claim will depend upon the value thereof.

§ 303.5 Conditions under which payments will be made if over $100.

If the amount standing to the credit of deceased amounts to the sum of $100 or more, payment will be made only to the executor or administrator of the estate, and upon the filing with the superintendent of a certified copy of letters of administration, or of the will as admitted to probate.

§ 303.6 Conditions under which payments will be made if under $100.

If the amount due deceased is less than $100, the claimant or claimants shall present an affidavit stating that they are the next of kin of deceased, naming the relationship, and are his legal heirs, and as such entitled to the personal estate left by him; and that, to the best of their knowledge and belief, deceased left no will bequeathing such property to any other person. This affidavit must be corroborated by that of two disinterested credible witnesses, who must have known claimant for at least 1 year, and must testify that he is the person he represents himself to be, and that they have reason to believe that he bears to the deceased the relationship claimed by him. The superintendent may require such further evidence in any case as he deems necessary. Payment shall be made by check in favor of the person entitled thereto, or, if there are several heirs, the check may be made payable to all jointly: *Provided*, That if the heirs in their affidavit filed with the superintendent shall authorize one of their number to receive payment, the check shall be drawn in favor of the person so authorized: *Provided also*, That in case of payments due minor children, the check may be drawn in favor of their father, mother, or legal guardian. In cases where the amount due the heirs of deceased is less than $10, the superintendent may, in his discretion, waive the requirement of an affidavit from the claimant, or of the corroborative affidavit, or both; but in all such cases the claimant shall be required to make a written statement that he is the heir of the deceased.

§ 303.7 Rights of relative who has incurred expense for deceased.

Where the amount due is less than $100, and it appears that some particular relative of deceased has incurred expense in providing him with clothing, luxuries, etc., during his residence in the hospital, the amount of such expenditure, when proved to the satisfaction of the superintendent, will be repaid to such relative, notwithstanding he may not be the legal or sole heir of deceased: *Provided*, That the heirs shall consent thereto.

§ 303.8 Recognition of an administrator.

In all cases where an administrator has been actually appointed, irrespective of the amount due deceased, payment shall be made to such administrator: *Provided*, That where it appears that such a payment would work hardship upon any near relative of the deceased, and the administrator was appointed in some jurisdiction outside of the District of Columbia, the superintendent may require ancillary letters of administration to be taken out in said District before making payment; or he may, in his discretion, make payment to such other person, having an interest in the estate of the deceased, as may be appointed administrator in said District, notwithstanding some other person may have previously been appointed in some other jurisdiction.

§ 303.9 Application of the statute of distributions of the District of Columbia.

For the purpose of determining the legal heirs of deceased, where the amount is less than $100 and no administrator has been appointed, the deceased shall be considered a resident of the District of Columbia, and payment shall be made according to the statute of distributions of said District (subchapter 8, chapter 5 of the Code of Laws for the District of Columbia), except as provided in § 303.7; and excepting that payment may be made to the heirs direct, the appointment of an administrator not being necessary.

PART 304—[RESERVED]

PART 305—AUTOPSIES

Sec.
305.1 Consent to autopsies.
305.2 Authorization for autopsies by Hospital superintendent.
305.3 Restrictions on autopsies.

Authority: R.S. 161, as amended, 72 Stat. 547; 5 U.S.C. 301.

Source: 25 FR 7739, Aug. 13, 1960, unless otherwise noted.

§ 305.1 Consent to autopsies.

An autopsy may be performed on the body of a deceased patient by direction of the superintendent of the Hospital or of an officer or employee of the Hospital designated by him where consented to in writing (a) by the surviving spouse of the decedent; or, if none such, (b) by the next of kin in the order of their relation: *Provided*, That where consent is granted by a member of a class of relatives consisting of more than one person, the consent of all members of such class shall be obtained. Documents embodying consent shall be made a part of the clinical record.

§ 305.2 Authorization for autopsies by Hospital superintendent.

Where the person authorized to give consent under § 305.1 cannot be located after diligent search and the Hospital assumes responsibility for burial arrangements, the superintendent of the Hospital may authorize the performance of an autopsy. Such authorization shall be made a part of the clinical record.

§ 305.3 Restrictions on autopsies.

Restrictions or limitations on the performance of or extent of the autopsy imposed by the consenting person or persons or by the decedent during his lifetime shall be observed.

PART 306—CONDUCT AND TRAFFIC REGULATIONS FOR THE SAINT ELIZABETHS HOSPITAL RESERVATION, WASHINGTON, D.C.

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306.27 Parking permits.
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Subpart D—Penalties

306.60 Penalties—other laws.

Authority: 24 U.S.C. 161.

Source: 40 FR 47765, Oct. 10, 1975, unless otherwise noted.

Subpart A—General

§ 306.1 Definitions.

As used in this part:

(a) The Saint Elizabeths Hospital reservation, Washington, D.C., hereinafter referred to as "the reservation" means those facilities and ground of Saint Elizabeths Hospital, Department of Health and Human Services located in Washington, D.C. as established by statute (24 USC 161) as a Federal reservation.

(b) "Security Force Officer" means a U.S. Special Policeman appointed pursuant to the provision of the Act of June 1, 1948, as amended (62 Stat. 281, 40 USC 318 et seq.).

(c) "Department" means the Department of Health and Human Services.

§ 306.2 Applicability.

The regulations in this part establish rules with respect to the parking and operation of vehicles and other activities and conduct on or within the reservation except that with respect to areas on the reservation used as living quarters, §§ 306.27, 306.28, 306.46, 306.49, and 306.50 shall not be applicable. These regulations are intended to supplement the rules and regulations regarding conduct on Federal Property adopted by the Department and set forth in the Department Facilities Engineering and Construction Manual as Exhibit X-3-335-1.

§ 306.3 Compliance with directions.

No person shall fail or refuse to comply with any order or direction of a Security Force Officer in connection with the direction, control or regulation of traffic and parking, or pursuant to any of the requirements of these regulations.

§ 306.4 Making or giving of false reports.

No person shall knowingly give any false or fictitious report or information to any authorized person investigating an accident or violation of law or these regulations.

Subpart B—Traffic and Vehicular Regulations

§ 306.20 Laws of District of Columbia applicable.

Unless otherwise specifically provided herein, the laws of the District of Columbia governing the use and operation of motor vehicles shall be applicable to the reservation.

§ 306.21 Inspection of license and regulation.

No person operating a motor vehicle on the reservation shall refuse to exhibit for inspection, upon request of a Security Force Officer, his operator's license or proof of ownership or registration.

§ 306.22 Speed limit.

No person shall drive any motor vehicle in excess of 15 mph on the reservation.

§ 306.23 Emergency vehicles.

No person shall fail or refuse to yield the right-of-way to an emergency vehicle when such emergency vehicle is operating with flashing lights or audible signal.

§ 306.24 Signs.

Every driver shall comply with all posted traffic and parking signs.

§ 306.25 Pedestrian traffic.

No person shall fail or refuse to yield the right-of-way to a pedestrian crossing the streets of the reservation.

§ 306.26 Parking.

(a) No person, unless otherwise authorized by a posted traffic sign, shall stand or park a vehicle—

(1) On any of the streets of the reservation;

(2) On a sidewalk;

(3) Within an intersection or within a cross walk;

(4) Within 15 feet of a fire hydrant, five feet of a driveway or 30 feet of a stop sign, yield sign, or traffic control device;

(5) At any place which would result in the vehicle being double parked;

(6) In a direction facing on-coming traffic;

(7) In or on any lawn area; or

(8) In a manner which would obstruct loading platforms, delivery areas, dumpsters or traffic.

(b) No person shall park a motor vehicle—

(1) Except within the lane painted or marked for such purpose or within the area designated and authorized for such purpose.

(2) In excess of 48 consecutive hours, unless permission has been granted by the Security Force.

§ 306.27 Parking permits.

No person, except visitors parking in areas identified by posted signs as reserved for visitors, shall park a motor vehicle on the reservation without having currently valid parking permit decals displayed on such motor vehicle in compliance with instructions of the issuing authority. Such parking decals may be revoked by the issuing authority for violation of any of the provisions of these regulations.

§ 306.28 Prohibited servicing of vehicles.

No person shall wash, polish, or make nonemergency repairs on privately-owned vehicles on the reservation without specific authority from the Superintendent, Saint Elizabeths Hospital.

§ 306.29 Unattended vehicles.

No person shall leave a motor vehicle unattended on the reservation with the engine running, the ignition unlocked, the key in the vehicle, or the brake ineffectively set.

Subpart C—Buildings and Grounds

§ 306.40 Closing the reservation.

As determined by the Superintendent, Saint Elizabeth's Hospital, the reservation may be closed to the public in emergency situations and at such other times as may be necessary for the orderly conduct of the Government's business. Admission to the reservation during periods when the reservation is closed to the public is limited to authorized individuals who may be required to sign a register and display identification when requested by a Security Force Officer or other authorized individual.

§ 306.41 Preservation of property.

No person shall, without authorization, willfully destroy or damage Federal property located on the reservation.

§ 306.42 Removal of property.

(a) No person shall remove Government property from the reservation, except under the policies and procedures of the Superintendent, Saint Elizabeths Hospital.

(b) No person shall remove from the reservation or any building thereon, privately-owned property, other than property ordinarily carried on the person, except upon establishing proper identification to a Security Force Officer or by following the procedures set forth in paragraph (a) of this section.

§ 306.43 Conformity with posted signs.

No person shall fail or refuse to comply with officially posted signs of prohibitory or directory nature, and, during emergencies, with the direction of any authorized individual.

§ 306.44 Nuisances.

No person shall willfully disrupt the Conduct of official business on the reservation, or engage in disorderly conduct; nor shall any person litter or dispose of rubbish in an unauthorized manner, throw articles of any kind from a building or climb upon any part of a building for other than authorized purposes.

§ 306.45 Gambling.

No person shall participate in games for money or other property, or in the operation of gambling devices, the conduct of lotteries or pools, or in the selling or purchasing of numbers tickets, or the taking or placing of bets.

§ 306.46 Intoxicating beverages and narcotics.

The consumption or use of intoxicating beverages, or narcotic drugs, except in connection with legal work assignments or in the course of professional treatment, or as otherwise authorized by the Superintendent, Saint Elizabeths Hospital, is prohibited.

§ 306.47 Weapons and explosives.

No person other than Federal, District of Columbia, State, or local law enforcement personnel so authorized, shall carry, transport, or otherwise possess on the reservation, firearms, other dangerous or deadly weapons or materials, or explosives, either openly or concealed.

§ 306.48 Nondiscrimination.

No person shall discriminate by segregation or otherwise against any other person(s) because of race, creed, color, sex, or national origin, in furnishing, or by refusing to furnish to such person(s) the use of any facility of a public nature, including all services, privileges, accommodations, and activities provided thereby on the reservation.

§ 306.49 Pets and other animals.

No person shall bring upon the reservation any cats, dogs, or other animals except as authorized by the Superintendent, Saint Elizabeths Hospital, provided however, that blind persons may have the use of seeing eye dogs.

§ 306.50 Sports and hobbies.

No person shall participate in any sport or hobby on the reservation unless authorized or except in designated areas.

§ 306.51 Cameras and photography.

Cameras are not permitted upon the reservation except as specifically authorized by the Superintendent, Saint Elizabeths Hospital. Photography for advertising and commercial purposes may be conducted only with the written permission of the Superintendent, Saint Elizabeths Hospital.

Subpart D—Penalties

§ 306.60 Penalties—other laws.

Whoever shall be found guilty of violating these regulations is subject to a fine of not more than $50 or imprisonment of not more than 30 days, or both (40 USC 318c). Except as expressly provided in this part, nothing contained in these regulations shall be construed to abrogate any other Federal laws or regulations, or any District of Columbia law or regulation applicable to the area in which the reservation is situated.

PARTS 307—399 [RESERVED]

FINDING AIDS

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Redesignation Table 1

The following table shows the effect of recodification on the regulations contained in Part 72 which appeared at 40 FR 5620, Feb. 6, 1975.

Old section	New section
72.1 (extracted)	1240.3, 1250.3
72.2	1240.54
72.3	1240.30
72.4	1240.10
72.11	1240.40
72.12	1240.50
72.13	1240.55
72.14	1240.57
72.15	1240.45
72.21	1240.70
72.22	1240.65
72.23	1240.75
72.24	1240.60
72.26	1240.62
72.101	1240.80
72.102	1240.83
72.103	1240.90
72.104	1240.95
72.105	1240.86
72.111	1250.80
72.112	1250.81
72.113	1250.82
72.114	1250.83
72.115	1250.84
72.116	1250.86
72.117	1250.85
72.118	1250.87
72.119	1250.89
72.120	1250.90
72.121	1250.93
72.122	1250.95
72.123	1250.96
72.131	1250.60
72.132	1250.61
72.133	1250.62
72.134	1250.63
72.135	1250.65
72.136	1250.67(a)
72.137	1250.67(b)
72.139	1250.67(c)
72.140	1250.70
72.141	1250.75
72.142	1250.79
72.146	1250.40
72.147	1250.41
72.148	1250.42
72.149	1250.44
72.150	1250.50
72.151	1250.45
72.152	1250.49
72.153	1250.43
72.154	1250.51
72.155	1250.53
72.156	1250.52
72.161	1250.20
72.162	1250.21
72.163	1250.22
72.164	1250.25
72.165	1250.26
72.166	1250.27
72.167	1250.28
72.168	1250.30
72.169	1250.33
72.170	1250.34
72.171	1250.39
72.172	1250.38
72.173	1250.32
72.174	1250.35
72.181	1240.20

Redesignation Table 2

At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section (Chapter I)	New section (Chapter IV)
Subpart A	*Part 460*
101.1	460.1
101.2	460.2
101.2a	460.2a
101.3	460.3
101.4	460.4
101.5	460.5
101.6	460.6
101.7	460.7
101.8	460.8
101.9	460.9
101.10	460.10
101.11	460.11
101.12	460.12
101.13	460.13
101.14	460.14
101.15	460.15
101.16	460.16
101.17	460.17
101.18	460.18
101.19	460.19
101.20	460.20
101.21	460.21
101.22	460.22
101.23	460.23
101.24	460.24
101.25	460.25
101.26	460.26
101.27	460.27
101.28	460.28
101.29	460.29
101.30	460.30
101.31	460.31
101.32	460.32
101.33	460.33
101.34	460.34
101.35	460.35
101.36	460.36
101.37	460.37
101.38	460.38
101.39	460.39
101.40	460.40
101.41	460.41
101.42	460.42
101.43	460.43
101.44	460.44
101.45	460.45
101.46	460.46
101.47	460.47
101.48	460.48
101.49	460.49
101.50	460.50
101.51	460.51
101.52	460.52
101.53	460.53
101.54	460.54
101.55	460.55
101.56	460.56
Subpart B	*Part 461*
101.101	461.1
101.102	461.2
101.103	461.3
101.104	461.4
101.105	461.5
101.106	461.6
101.107	461.7
Subpart N	*Part 473*
101.1401	473.1
101.1402	473.2
101.1403	473.3
101.1404	473.4
101.1405	473.5
101.1406	473.6
Subpart U	*Part 480*
101.2101	480.1
101.2102	480.2
101.2103	480.3
101.2104	480.4
101.2105	480.5
101.2106	480.6

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963 and 1964-1972," published in three separate volumes.

1973

42 CFR

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71.1 (w) revised	16861
71.31 Revised	16861
(a)(1) corrected	19222
71.46 Revised	16861
71.49 (a) revised	16862
74.1 (i) revised	10721
74.10 (d) revised	10721
74.20 (a), (c), and (d) revised	10721, 10722
74.21 (a) and (b) revised	10722
74.42 (d) revised	10722
74.47 Heading revised	10722
78 Redesignated as 21 CFR Part 278	1926
80 Added	16645
84 Added	11459
84.2 (e) corrected	14940
87.14 (b) amended; (c) revised	26199
87.15 Removed	26199
87.20 (a) amended	26199
87.30 Amended	26199
87.32 Removed	26199
87.33 Removed	26199
87.34 Revised	26199
87.40-87.41 (Subpart E) Added	26200
91.6 (b) amended; (c) revised	26200
91.8 (a) amended	26200
91.13 Amended	26200
91.14 (b) and (c)(2) and (3) removed; (d)(2) revised	26200
91.15 Removed	26200
91.17 Revised	26200

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205.4 (b) and (d) revised	26201
205.6 Revised	26201

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Chapter II—Continued

	38 FR Page
205.7 Amended	26201
205.8 Removed	26201
205.9 Removed	26201
205.10 (a) revised; (b) removed; (c) amended	26201
205.13 Removed	26201
205.14 Removed	26201
205.15 Revised	26201
205.16 (b) removed	26201
205.18 Added	26201
206.5-206.7 (Subpart B) Removed	26201
208 Removed	26201

1973–1974

(Regulations published from October 1, 1973 through September 30, 1974)

42 CFR

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	38 (39*) FR Page
62 Added	*17962
65 Added	28290
100 Added	31381
100.102 (e) amended	*32029
100.110 (a)(1) revised	*32030
100.106 (c)(2) corrected	32789
101 Added	*10205
101.7 Amended	*23060
101.36 Amended	*23060
101.37 Amended	*23060
101.101-101.106 (Subpart B) Added	*16202
200 Revised and redesignated as Subpart A of Part 51a	*26692

NOTE: Symbol (*) refers to 1974 page numbers.

1974–1975

(Regulations published from October 1, 1974 through September 30, 1975)

42 CFR

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	39 (40†) FR Page
66 Added	†19314
66.113 (b) Technical correction	†20953
66.116 (b)(2) corrected	†20953
71.154 Revised	†33660
71.155 Revised	†33661
71.181-71.189 (Subpart J-3) Added	†33661
72 Redesignated in part as Title 21 Parts 1240, 1250; see redesignation table	†5620
86 Added	†29077
110 Added	37311
110.102 (a)(9) and (10) removed, (b)(9) and (10) corrected	41095
110.201 Corrected	41095
110.203 (k) corrected	41095
110.301-110.305 (Subpart C) Heading corrected	41095
110 (Subpart H) Heading corrected	41095
110.601-110.605 (Subpart F) Added	†33520

1975–1976

(Regulations published October 1, 1975 through September 30, 1976)

42 CFR

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	40 (41Δ) FR Page
67 Added	Δ5226
101.2a Added	Δ33436
101.101 (a) amended; (c) added	Δ17865
101.103 Amended	Δ17865
101.104 Introductory text revised	Δ17865
101.1401-101.1406 (Subpart N) Added	Δ7878
101.2101-101.2106 (Subpart U) Added	Δ28687
110.502 (a) revised	Δ33557
110.801-110.808 (Subpart H) Added	50213
122 (Subchapter K) Added	Δ12824
122.105 (b)(1) revised	Δ31208
Effective date corrected	Δ34749
122.106 (b) revised	Δ31209

42 CFR—Continued

Chapter I—Continued

	40 (41Δ) FR Page
122.204 (b) revised	Δ41089
122.209 (a) corrected	Δ23386
123 Added	Δ22525

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203 Removed	54107

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306 Added	47765

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(Regulations published from October 1, 1976 through September 30, 1977)

42 CFR

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66.102 (j) revised	*29483
82 Added	44396
82.4 Corrected	49636
82.15 (a) corrected	49636
82.64 (g) corrected	49636
85a Added	45002
86.10 (c) added	*52401
86.11 (b) revised	*52401
86.13 (c) added	*52401
86.14(c)-(e) redesignated as (d)-(f); new (c) added	52402
100 Policy statement	*4847
100.102 (e) revised	*4024
101 Redesignated as Title 42 Parts 460-480	*52826
101.27 Revised	*48337
101.39 Revised	*42858, 43084
101.1401-101.1406 (Subpart N) Revised	*4677
110 Authority citation revised	*29401
110.101-110.110 (Subpart A) Revised	*29401
110.201-110.214 (Subpart B) Revised	*29407
110.301-110.305 (Subpart C) Revised	*29409
110.401-110.407 (Subpart D) Revised	*29410
110.501-110.508 (Subpart E) Revised	*29413
110.601-110.605 (Subpart F) Revised	*29414
110.602 (b) corrected	*32234
122.204 (b) revised	*18279
122.301-122.310 (Subpart D) Added	*4024

NOTE: Symbol (†) refers to 1975 page numbers.

NOTE: Symbol (Δ) refers to 1976 page numbers.

NOTE: Symbol (*) refers to 1977 page numbers.

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122.304 (a)(3) revised	*18606
122.308 Technical correction	*7955
122.309 Revised	*18606
123.401-123.411 (Subpart E) Added	*4028
123.404 (a)(3) revised	*18607
123.409 Technical correction	*7955
123.410 Revised	*18607

1977–1978

(Regulations published from October 1, 1977, through September 30, 1978)

42 CFR

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62 Added	†29784
66 Revised	63389
66.106 Heading correctly added	†1498
67.10-67.28 (Subpart A) Added	†34472
82 Removed	†33247
84 Removed	†33247
110.301-110.305 (Subpart C) Revised	†6023
110.401-110.407 (Subpart D) Revised	†6026
110.501-110.508 (Subpart E) Revised	†6021
110.801-110.808 (Subpart H) Revised	†17682
110.901-110.907 (Subpart I) Added	†32255
121 Added	†13044
122.1 (o)(1) amended	†1253
122.106 (c) revised	62270
122.109 (b)(2)(i) and (ii) amended; (b)(3)(i) revised	†1253
123 Revised	†10120
124 Added	62270
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300 Removed	†29005
304 Removed	†29005

1978–1979

(Regulations published from October 1, 1978, through September 30, 1979)

42 CFR

	43 (44Δ) FR Page
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66.102 (k) revised	55763

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	43 (44Δ) FR Page
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71.151 Revised	53039
75 Removed	Δ30341
90 Removed	Δ45946
91 Revised	Δ12035
100.103 (a)(2)(iv) amended; interim	Δ24429
100.110 Removed	Δ44846
Removal effective date corrected	Δ45946
110.101—110.110 (Subpart A) Revised; interim	Δ42063
110.201—110.212 (Subpart B) Revised	Δ42076
110.402 (b)(2)(ii) revised	Δ50183
110.502 (c) added; interim	Δ10603
110.507 (a)(1) and (2) added; interim	Δ10603
110.809 Added	Δ42082
122.301—122.310 (Subpart D) Revised	Δ19315
122.304 (a)(5) added; interim	Δ24430
122.401—122.415 (Subpart E) Added; eff. 11-8-79	Δ47084
122.402 Corrected	Δ49454
122.408 Heading, (b) introductory text and (3) corrected	Δ49455
122.409 (b)(1) and (2) corrected	Δ49455
122.412 (a)(10)(ii) and (12) corrected	Δ49455
122.413 (a) corrected	Δ49455
123.401—123.411 (Subpart E) Added	Δ19320
123.404 (a)(5) added; interim	Δ24430
124.200—124.203 (Subpart C) Added	45739
124.501—124.512 (Subpart F) Added	Δ29375
124.601—124.607 (Subpart G) Added	Δ29379
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205—206 (Chapter II) Removed	Δ26745
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205 Removed	Δ26745
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206 Removed	Δ26745
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NOTE: Symbol (*) refers to 1977 page numbers.

NOTE: Symbol (†) refers to 1978 page numbers.

NOTE: Symbol (Δ) refers to 1979 page numbers.

1979–1980

(Regulations published from October 1, 1979, through September 30, 1980)

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62	Revised	*55429
66	Revised	*1822, *64816
66.111	(c)(3) corrected	*9742
66.204	(b)(6) corrected	*9742
66.205	(b) corrected	*9742
66.207	Corrected	*9742
67	Incorporation by reference approvals	*64816
71.102	Revised	*58912
71.154	Revised	*12253
72	Revised	*48627
74	Incorporation by reference approvals	*64816
74.10	(d) removed	*26960
85	Authority citation revised	*2652
85.1	Revised	*2652
85.2	Revised	*2652
85.3	Revised	*2653
85.3-1	Added	*2653
85.4	Revised	*2653
85.5	Revised	*2653
85.7	(a), (b), and (c) amended	*2653
85.10	Amended	*2653
85.11	(a) and (e) revised, (d) amended	*2653
85.12	Revised	*2654
85a	Authority citation revised	*2654
85a.1	(a) revised	*2654
85a.2	Introductory text, (a), (d), and (i) revised; (j) through (m) added	*2654
85a.3	(a) amended	*2654
85a.4	(a)(1) and (3) revised; (a)(2), (b) and (c) amended; (a)(4) added	*2654
85a.5	(b)(1) and (e) amended	*2654
85a.7	Amended	*2654
86	Incorporation by reference approvals	*64816
110	Interpretations	*28654
	Document classification corrected	*31721, *64816
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110.205	Removed; new 110.205 redesignated from 110.206; existing text designated as (a); (b) added	*55122
110.206	Redesignated as 110.205 and amended; new 110.206 redesignated from 110.208	*55122, 55123
110.207	Removed; new 110.207 redesignated from 110.209 and revised	*55123
110.208	Redesignated as 110.206; new 110.208 added	*55123
110.209	Redesignated as 110.207 and revised; new 110.209 redesignated from 110.210 and revised	*55123
110.210	Redesignated as 110.209 and revised; new 110.210 redesignated from 110.211 and revised	*55123
110.211	Redesignated as 110.210 and revised; new 110.211 redesignated from 110.212	*55123
110.212	Redesignated as 110.211	*55123
110.401	Revised	*6059
110.402	Revised	*6059
110.404	(f) introductory text amended; (f)(4) revised	*6059
110.405	(b)(1) and (2) revised; (b)(4) amended	*6059
110.501—110.508	(Subpart E) Heading amended	*6060
110.502	(a) revised; (d) added	*6060
110.503	(b) amended	*6060
110.505	(b) amended	*6060
110.1001—110.1016	(Subpart J) Added; interim	*24353
122	Incorporation by reference approvals	*64816
122.204A	Added; interim	*59133
122.501—122.508	(Subpart F) Added	71769
123.601—123.608	(Subpart G) Added	71771
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Note: Symbol (*) refers to 1980 page numbers.

1980–1981

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42 CFR

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64a Added	†39979
66 Incorporation by reference approvals	†47938
67 Incorporation by reference approvals	†47938
74 Incorporation by reference approvals	72464
Incorporation by reference approvals	†47938
74.10 (d) removal effective date confirmed	76148
86 Incorporation by reference approvals	†47938
110 Incorporation by reference approvals	72464
Incorporation by reference approvals	†47938
Interpretations	†13511
Interpretations corrected	†15141
Effect of statutory amendment	45694
110.101—110.111 (Subpart A) Revised	72528
110.104 (b) corrected	77031
110.108 (c) corrected	80531
(c) revised; (s) added	†6355
(c) and (s) effective date deferred	†14015
(c) (1), (2), and (s) effective date confirmed	†21999
110.801—110.810 (Subpart H) Revised	72517
122 Incorporation by reference approvals	†47938
122.301—122.311 (Subpart D) Revised	69742
123.401—123.413 (Subpart E) Revised	69745
124 Incorporation by reference approvals	†47938

NOTE: Symbol (†) refers to 1981 page numbers.

1981–1982

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42 CFR

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87 Revised	58676
91 Removed; eff. 10-1-82	48593
91.5 (c) introductory text and (4)(i) amended; (c)(3) revised; (c)(7) and (10) removed; interim	48597
100 Policy statement revised	61287
100.106 Interpretation	Δ7230
110 Effect of statutory amendments	45694, 51246
110.101 Amended	Δ19338
110.103 (a) revised; (c) removed	Δ19339
110.104 (a)(3) revised; (b) removed; (c) through (g) redesignated as (b) through (f); new (b)(2) revised	Δ19339
110.105 (b) revised	Δ19339
110.107 (b) introductory text revised; (b)(1) amended	Δ19340
110.108 (a)(3) added; (d), (e), and (l) through (n) removed; (f) through (k) and (o) through (s) redesignated as (d) through (i) and (j) through (n); (b) and new (j)(2) revised	Δ19340
110.211 (b) amended	Δ19340
110.302 (a) amended	Δ19341
110.402 Introductory text amended	Δ19341
110.407 (c) revised	Δ19341
110.503 (a)(2) and (b)(1) amended; (a)(3) removed; (b)(2) revised	Δ19341
110.507 (a) introductory text removed; (a) (1) and (2) redesignated as (a)	Δ19341
110.508 (c) revised	Δ19341
110.601—110.605 (Subpart F) Revised	Δ31667
110.603 (b)(2)(i) and (ii), and (e) corrected	Δ35194

NOTE: Symbol (Δ) refers to 1982 page numbers.

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110.605 Correctly designated; (a) corrected....Δ35194
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110.805 (a) (1) and (2) amended....Δ19341
110.903 (a) amended....Δ19341
110.904 (d)(1) amended....Δ19341
110.1003 (b) amended; (c) removed....Δ19341
110.1004 Revised (effective date pending)....Δ19342
110.1006 (a) amended; (b)(2) revised....Δ19342
110.1007 (b)(2) revised....Δ19342
110.1009 Removed; new 110.1009 redesignated from 110.1013 and revised....Δ19342

Note: Symbol (Δ) refers to 1982 page numbers.

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110.1010 Removed; new 110.1010 redesignated from 110.1014...Δ19342
110.1011 Removed; new 110.1011 redesignated from 110.1016...Δ19342
110.1012 Removed....Δ19342
110.1013 Redesignated as 110.1009 and revised....Δ19342
110.1014 Redesignated as 110.1010....Δ19342
110.1015 Removed....Δ19342
110.1016 Redesignated as 110.1011....Δ19342
122.104 (b)(1)(iii)(D) removed...Δ28652
122.107 (c)(15) and (17) revised; (c)(19) added....Δ3552
122.109 (b) revised....Δ28651
122.701—122.707 (Subpart H) Added; interim....Δ30951
124 Interpretation....Δ17489

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